Adverse events should be reported. Reporting forms and information can be found at https://yellowcard.mhra.gov.uk/

Adverse events should also be reported to McNeil Products Limited on 00800 555 22000

Product Name (click hyperlink to go to product)	**PL Number**	**Legal Category**	**RRP (ex-VAT)**	**NHS Price**
Nicorette Invisi 10 mg Patch	PL 15513/0159	GSL	7's £17.69	7's £11.85
Nicorette Invisi 15 mg Patch	PL 15513/0160	GSL	7's £17.68	7's £11.84
Nicorette Invisi 25 mg Patch	PL 15513/0161	GSL	7's £17.69	7's £11.85
			14's £29.05	14's £20.99
Nicorette QuickMist 1mg/spray Mouthspray	PL 15513/0357	GSL	1 dispenser pack £23.24	1 dispenser pack £15.57
			2 dispenser pack £39.52	2 dispenser pack £26.48
			6 dispenser pack £108.46	N/A
Nicorette Quickmist SmartTrack 1mg/spray Mouthspray		GSL	1 dispenser pack £23.24	1 dispenser pack £15.57
			2 dispenser pack £39.52	2 dispenser pack £26.48
Nicorette QuickMist Cool Berry 1mg/spray Mouthspray	PL 15513/0395	GSL	1 dispenser pack £23.24	1 dispenser pack £15.57
			2 dispenser pack £39.52	2 dispenser pack £26.48
Nicorette QuickMist Cool Berry SmartTrack 1mg/spray Mouthspray		GSL	2 dispenser pack £39.52	N/A
Nicorette QuickMist SpearMint 1mg/spray Mouthspray	PL 15513/0416	GSL	1 dispenser pack £23.24	1 dispenser pack £15.57
		GSL	2 dispenser pack £39.52	2 dispenser pack £26.48

Nicorette® 15 mg Inhalator	PL 15513/0358	GSL	4-cartridge pack £10.90	4-cartridge pack £7.42
			20-cartridge pack £39.10	20-cartridge pack £26.58
			36-cartridge pack £60.67	36-cartridge pack £41.25
Nicorette 2 mg Gum	PL 15513/0169	GSL	105's £18.47	105's £12.37
			210's £30.02	210's £20.11
Nicorette 4 mg Gum	PL 15513/0170	GSL	105's £22.59	105's £15.14
			210's £37.14	210's £24.89
Nicorette Icy White 2 mg Gum	PL 15513/0152	GSL	30's £7.45	30's £5.44
			105's £18.47	105's £12.37
			210's £30.02	210's £20.11
Nicorette Icy White 4 mg Gum	PL 15513/0153	GSL	105's £22.59	105's £15.14
Nicorette Fruitfusion 2 mg Gum	PL 15513/0136	GSL	30's £7.45	30's £5.44
			105's £18.47	105's £12.37
Nicorette Fruitfusion 4 mg Gum	PL 15513/0137	GSL	105's £22.59	105's £15.14
Nicorette Freshmint 2 mg Gum	PL 15513/0173	GSL	30's £7.45	30's £5.44
			105's £18.47	105's £12.37
			210's £30.02	210's £20.11
Nicorette Freshmint 4 mg Gum	PL 15513/0174	GSL	105's £22.59	105's £15.14
			210's £37.14	210's £24.89
Nicorette Cools 2 mg Lozenge	PL 15513/0374	GSL	40's (1x40) pack £9.52	40's (1x40) pack £7.37
			80's (2x40) pack £17.99	80's (2x40) pack £12.05
			160's (4x40) pack £32.38	160's (4x40) pack £21.70

Nicorette Cools 4 mg Lozenge	PL 15513/0375	GSL	80's (2x40) pack £18.16	80's (2x40) pack £12.17
Nicorette Fruit 2 mg Lozenge	PL 15513/0393	GSL	40's (1x40) pack £9.52	40's (1x40) pack £7.37
			80's (2x40) pack £17.99	80 (2x40) pack £12.05
			160's (4x40) pack £32.38	160's (4x40) pack £21.70
Nicorette Fruit 4 mg Lozenge	PL 15513/0394	GSL	160's (4x40) pack £32.38	160's (4x40) pack £21.70
Nicorette Microtab 2 mg sublingual tablet	PL 15513/0178	GSL	100's £29.70	100's £19.90
Nicorette Nasal Spray	PL 15513/0180	GSL	10ml £32.68	10ml £21.89

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Nicorette Invisi 10 mg Patch
NicAssist Translucent 10 mg Patch

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each patch is 9 sq.cm, containing nicotine 1.75 mg/sq.cm, releasing a nominal 10 mg of nicotine per 16 hours.
For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Transdermal patch.
Semi-transparent, beige, imprinted 9 cm^2 rectangular TTS with rounded corners. Centrally located on a rectangular, aluminized and siliconised release liner.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Nicorette Invisi Patch relieves and/or prevents craving and nicotine withdrawal symptoms in nicotine dependence, such as those arising from the use of tobacco or electronic cigarettes. It is indicated to aid quitting or reduction prior to quitting, to assist those who are unwilling or unable to use such products, and as a safer alternative to smoking tobacco for smokers and those around them.

Nicorette Invisi Patch is indicated in pregnant and lactating women making a quit attempt (see section 4.6).

4.2 Posology and method of administration

When making a quit attempt behavioural therapy, advice and support will normally improve the success rate.
It is intended that the patch is worn through the waking hours (approximately 16 hours) being applied on waking and removed at bedtime.

Smoking/Vaping Cessation
Adults (over 18 years of age)
For best results, most smokers/vapers are recommended to start on 25 mg / 16 hours patch (Step 1) and use one patch daily for 8 weeks. Gradual weaning from the patch should then be initiated. One 15 mg/16 hours patch (Step 2) should be used daily for 2 weeks followed by one 10 mg/16 hours patch (Step 3) daily for 2 weeks.

	Dose	Duration
Step 1	Nicorette Invisi 25 mg Patch	First 8 weeks
Step 2	Nicorette Invisi 15 mg Patch	Next 2 weeks
Step 3	Nicorette Invisi 10 mg Patch	Last 2 weeks

Lighter smokers (i.e. those who smoke less than 10 cigarettes per day) and light to moderate vapers (e.g. vape infrequently or use low strength e-liquid) are recommended to start at Step 2 (15 mg) for 8 weeks and decrease the dose to 10 mg for the final 4 weeks.

Those who experience excessive side effects with the 25 mg / 16 hours patch (Step 1), which do not resolve within a few days, should change to a 15 mg / 16 hours patch (Step 2). This should be continued for the remainder of the 8 week course, before stepping down to the 10 mg / 16 hours patch (Step 3) for 4 weeks. If symptoms persist the advice of a healthcare professional should be sought.

Adolescents (12 to 18 years)
The dose and method of use are as for adults however as data are limited in this age group, the recommended treatment duration is 12 weeks. If longer treatment is required, advice from a healthcare professional should be sought.

Smoking/Vaping Reduction/Pre-Quit
Smokers/vapers are recommended to use the patch to prolong smoke/vape- free intervals and with the intention to reduce smoking/vaping as much as possible.

The starting dose should follow the smoking/vaping cessation instructions above i.e. 25 mg (Step 1) is suitable for those who smoke 10 or more cigarettes per day or heavy vapers (e.g. vape frequently or use high strength e-liquid. Lighter smokers (i.e. those who smoke less than 10 cigarettes per day) and light to moderate vapers (e.g. vape infrequently or use low strength e-liquid) are recommended to start at Step 2 (15 mg).

Smokers/vapers starting on 25 mg patch (Step 1) should transfer to 15 mg patch (Step 2) as soon as cigarette consumption reduces to less than 10 cigarettes per day or vaping dependency decreases.

A quit attempt should be made as soon as the smoker/vaper feels ready. When making a quit attempt patients who have reduced to less than 10 cigarettes per day are recommended to continue at Step 2 (15 mg) for 8 weeks and decrease the dose to 10 mg (Step 3) for the final 4 weeks. When vapers have reduced their dependency sufficiently (e.g. vape infrequently or use low strength e-liquid), they should continue at Step 2 (15 mg) for 8 weeks and then step down to 10 mg (Step 3) for the final 4 weeks.

Temporary Abstinence
Use a Nicorette Invisi Patch in those situations when you can't or do not want to smoke/vape for prolonged periods (greater than 16 hours).

For shorter periods then an alternative intermittent dose form would be more suitable (e.g. Nicorette inhalator or gum).

Smokers of 10 or more cigarettes per day or heavy vapers (e.g. vape frequently or use high strength e-liquid) are recommended to use 25 mg patch. Lighter smokers (i.e. those who smoke less than 10 cigarettes per day) and light to moderate vapers (e.g. vape infrequently or use low strength e-liquid) are recommended to use 15 mg patch.

How to apply the patches
Nicorette Invisi Patch should be applied to clean, dry intact areas of hairless skin, for example on the hip, upper arm, or chest. These areas should be varied each day, and the same site should not be used on consecutive days.

1. Wash your hands before applying the patch.
2. Cut open the pouch with scissors along the side, as indicated. Select a clean, dry, hairless intact area of skin, such as the hip, upper arm or chest.
3. Peel one part of the silvery aluminium backing away. Avoid touching the sticky surface of the patch with your fingers.
4. Apply the sticky part of the patch carefully onto the skin and peel off the remaining half of the silvery aluminium backing.
5. Press the patch firmly onto the skin with your palm or fingertips.
6. Rub your fingers firmly round the edge to ensure that the patch sticks firmly.

Use of skin oils or talc can prevent proper adhesion of the patch.

After removal, used patches should be disposed of carefully.

4.3 Contraindications

Nicorette Invisi Patches should not be administered to patients with known hypersensitivity to nicotine or any component of the patch.

4.4 Special warnings and precautions for use

Any risks that may be associated with NRT are substantially outweighed by the well-established dangers of continued smoking. The risks of continued vaping are not yet established.

A risk-benefit assessment should be made by an appropriate healthcare professional for patients with the following conditions:
Underlying cardiovascular disease: In stable cardiovascular disease this product presents a lesser hazard than continuing to smoke. However dependent smokers currently hospitalised as a result of myocardial infarction, unstable or worsening angina including Prinzmetal angina, severe dysrhythmia or CVA and who are considered to be haemodynamically unstable and/or who have uncontrolled hypertension should be encouraged to

stop smoking with non-pharmacological interventions. If this fails, this product may be considered, but as data on safety in this patient group are limited, initiation should only be under medical supervision. The risks of continued vaping are not yet established.

Diabetes mellitus: Patients with diabetes mellitus should be advised to monitor their blood sugar levels more closely than usual when quitting and NRT is initiated as reductions in nicotine induced catecholamine release can affect carbohydrate metabolism.

Renal or hepatic impairment: This product should be used with caution in patients with moderate to severe hepatic impairment and/or severe renal impairment as the clearance of nicotine or its metabolites may be decreased with the potential for increased adverse effects.

Seizures: Potential risks and benefits of nicotine should be carefully evaluated before use in subjects with a history of epilepsy as cases of convulsions have been reported in association with nicotine.

Danger in children: Doses of nicotine tolerated by adult and adolescent smokers or vapers can produce severe toxicity in children that may be fatal. Products containing nicotine should not be left where they may be misused, handled or ingested by children. After removal, the patch should be folded in half, adhesive side innermost, and placed inside the opened sachet, or in a piece of aluminium foil. The used patch should then be disposed of carefully, away from the reach of children or animals.

Phaeochromocytoma and uncontrolled hyperthyroidism: As nicotine causes release of catecholamines, this product should be used with caution in patients with uncontrolled hyperthyroidism or phaeochromocytoma.

Transferred dependence: Transferred dependence is rare and is both less harmful and easier to break than smoking dependence.
Stopping smoking: Polycyclic aromatic hydrocarbons in tobacco smoke induce the metabolism of drugs metabolised by CYP 1A2 (and possibly by CYP 1A1). When a smoker stops smoking, this may result in slower metabolism and a consequent rise in blood levels of such drugs. This is of potential clinical importance for products with a narrow therapeutic window, e.g. theophylline, clozapine and ropinirole.

Gastrointestinal Disease: Nicotine may exacerbate symptoms in patients suffering from oesophagitis, gastric or peptic ulcers and NRT preparations should be used with caution in these conditions.

Generalised dermatological disorders: Patients with chronic generalised dermatological disorders such as psoriasis, chronic dermatitis or urticaria should not use this product.

Angioedema and urticaria have been reported.
Erythema may occur. If it is severe or persistent, treatment should be discontinued.

Minor skin reactions are seen at the patch application site in a proportion of patients when commencing treatment (see also section 4.8). If skin reactions become more severe or more generalized, patients should be advised to discontinue use of patches and seek further medical help regarding nicotine replacement therapy.

This product should be removed prior to undergoing any Magnetic Resonance Imaging (MRI) procedures to prevent the risk of burns.

4.5 Interaction with other medicinal products and other forms of interaction

No clinically relevant interactions between nicotine replacement therapy and other drugs have definitely been established. However nicotine may possibly enhance the haemodynamic effects of adenosine i.e. increase in blood pressure and heart rate and also increase pain response (angina-pectoris type chest pain) provoked by adenosine administration.

4.6 Fertility, pregnancy and lactation

Pregnancy
Stopping smoking is the single most effective intervention for improving the health of both the pregnant smoker and her baby, and the earlier abstinence is achieved the better. Ideally smoking cessation during pregnancy should be achieved without NRT. Nicotine passes to the foetus and affects its breathing movements and circulation. The effect on the circulation is dose-dependent. However, if the mother cannot (or is considered unlikely to) quit without pharmacological support, NRT may be used as the risk to the foetus is lower than that expected with smoking tobacco. Stopping completely is by far the best option but if this is not achievable Nicorette Invisi Patch may be used in pregnancy as a safer alternative to smoking. Because of the potential for nicotine-free periods, intermittent dose forms are preferable, but patches may be considered as an alternative if there is significant nausea and/or vomiting. If patches are used they should, if possible, be removed at night when the foetus would not normally be exposed to nicotine.

There is no or limited data regarding the effect of vaping in pregnancy.

Use of NRT by the pregnant smoker/vaper should only be initiated after advice from a health care professional.

Lactation
Nicotine should be avoided during breast-feeding. The relatively small amounts of nicotine found in breast milk during NRT use are less hazardous to the infant than second-hand smoke. Intermittent dose forms would minimize the amount of nicotine in breast milk and permit feeding when levels were at their lowest.

There is no or limited data regarding the effect of vaping in lactating women.

Use of NRT by breast feeding smokers/vapers should only be initiated after advice from a health care professional.

Fertility
In females tobacco smoking delays time to conception, decreases in-vitro fertilization success rates, and significantly increases the risk of infertility.

In males tobacco smoking reduces sperm production, increases oxidative stress, and DNA damage. Spermatozoa from smokers have reduced fertilizing capacity.

The specific contribution of nicotine to these effects in humans is unknown.

There is no or limited data regarding the effect of vaping on fertility.

4.7 Effects on ability to drive and use machines

This product has no or negligible influence on the ability to drive and use machines.

4.8 Undesirable effects

Effect of Smoking Cessation
Some symptoms may be related to nicotine withdrawal associated with stopping smoking. These can include irritability/aggression, dysphoria/depressed mood, anxiety, restlessness, poor concentration, increased appetite/weight gain, urges to smoke (cravings), night-time awakenings/sleep disturbance, decreased heart rate, dizziness, presyncopal symptoms, cough, constipation, gingival bleeding or nasopharyngitis. Increased frequency of aphthous ulcer may occur after abstinence from smoking. The causality is unclear.

Effects of Vaping Cessation
The nicotine withdrawal effects of vaping cessation have not been established; however it is anticipated that many of the effects relating to nicotine withdrawal will be the same as those seen with tobacco smoking cessation.

Adverse Drug Reactions (ADRs)
This product may cause adverse reactions similar to those associated with nicotine given by other means, including smoking and vaping, and these are mainly dose-dependent. At recommended doses this product has not been found to cause any serious adverse effects. Excessive use of this product by those who have not been in the habit of inhaling tobacco smoke or vaping could possibly lead to nausea, faintness or headaches.

Most of the undesirable effects reported by the subjects occur during the early phase of treatment and are mainly dose dependent.
About 20% of Nicorette Invisi Patch users experience mild local skin reactions, during the first weeks of treatment. In some patients the skin

reactions may become more severe e.g. skin blistering or burning sensation or may be more generalized (see section 4.4).

Allergic reactions (including symptoms of anaphylaxis) occur rarely during use of this product.

Adverse events observed in patients treated with nicotine patch formulations during clinical trials and post-marketing surveillance are listed below by system organ class (SOC).

*Frequencies are defined in accordance with current guidance, as: *very common (≥1/10); common (≥1/100, <1/10); uncommon (≥1/1 000, <1/100); rare (≥1/10 000, <1/1 000); very rare (<1/10 000), not known - cannot be estimated from the available data. ** Frequency category estimated using the "Rule of 3"

Body System	**Reported adverse event (Preferred Term)**	**Incidence***
Immune system disorders	Hypersensitivity[a#]	Uncommon
	Anaphylactic reaction[a]	Rare**
Nervous system disorders	Dizziness Headache[a§]	Common
	Paraesthesia[a#]	Uncommon
	Seizures	Not known
Cardiac disorders	Palpitations[a] Tachycardia[a]	Uncommon
	Reversible atrial fibrillation	Very rare
Vascular disorders	Flushing[a] Hypertension[a]	Uncommon
Respiratory, Thoracic and Mediastinal Disorders	Dyspnoea[a]	Uncommon
Gastrointestinal disorders	Nausea[a§] Vomiting[a]	Common
	Gastrointestinal discomfort[a]	Rare**

Body System	Reported adverse event (Preferred Term)	Incidence*
Skin and subcutaneous tissue disorders	Pruritus	Very common
	Rash[a] Urticaria[a]	Common
	Hyperhidrosis[a]	Uncommon
	Angioedema[a] Erythema[a]	Rare**
Musculoskeletal and Connective Tissue Disorders	Myalgia[b]	Uncommon
	Pain in extremity	Rare**
General disorders and administration site conditions	Application site reactions Asthenia[a] Chest discomfort and pain[a] Malaise[a] Fatigue[a#§]	Uncommon

[a] Systemic effects; [b] In vicinity/region of patch

[#] Although the frequency is <1% the PT occurred at a frequency ≥1% in another formulation in which the PT was identified as a systemic ADR.

[§] Although the frequency in the active group is less than that of the placebo group, the frequency in the specific formulation in which the PT was identified as a systemic ADR was greater in the active group than the placebo group.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

4.9 Overdose

Symptoms: Symptoms of overdose with nicotine from this product may occur in smokers/vapers who have previously had a low nicotine intake from cigarettes/e-cigarettes or if other sources of nicotine are used concomitantly with this product.

Acute or chronic toxicity of nicotine in man is highly dependent on mode and route of administration. Adaptation to nicotine (e.g. in smokers/vapers) is known to significantly increase tolerability compared with non-smokers/vapers.

The minimum lethal dose of nicotine in a non-tolerant man has been estimated to be 40 to 60 mg. Symptoms of acute nicotine poisoning include nausea, vomiting, increased salivation, abdominal pain, diarrhoea, sweating, headache, dizziness, disturbed hearing and marked weakness. In extreme cases, these symptoms may be followed by hypotension, rapid or weak or irregular pulse, breathing difficulties, prostration, circulatory collapse and terminal convulsions.

Management of an overdose: All nicotine intake should stop immediately and the patient should be treated symptomatically. Remove the patch and rinse the application site with water. Artificial respiration should be instituted if necessary. Activated charcoal reduces the gastro-intestinal absorption of nicotine.

Doses of nicotine that are tolerated by adult smokers/vapers during treatment may produce severe symptoms of poisoning in children and may prove fatal. Suspected nicotine poisoning in a child should be considered a medical emergency and treated immediately.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Drug used in nicotine dependence.
ATC code: N07B A01

Nicotine has no therapeutic uses except as replacement therapy for the relief of abstinence symptoms in nicotine-dependent smokers/vapers.

Owing to its many actions, the overall effects of nicotine are complex. A wide variety of stimulant and depressant effects are observed that involve the central and peripheral nervous, cardiovascular, endocrine, gastro-intestinal and skeletal motor systems. Nicotine acts on specific binding sites or receptors throughout the nervous system.

Increased appetite is a recognised symptom of nicotine withdrawal and post-cessation weight gain is common. Clinical trials have demonstrated that Nicotine Replacement Therapy can help control weight following a quit attempt.

5.2 Pharmacokinetic properties

The patches are labelled by the average amount of nicotine released over 16 hours.

A linear relationship exists between released amount of nicotine (dose) and plasma levels of nicotine over the therapeutic dose range, 10-25 mg/16 hours The mean peak plasma levels of nicotine (C_{max}) achieved are calculated to:

Dose nicotine (mg/16 hours)	C_{max} (ng/ml)
10	10
15	15.5
25	26.5

The calculated peak plasma levels are in the same range as true measured peak plasma concentrations: 11 ng/mL for the 10 mg patch and 25 ng/mL for the 25 mg patch. Interpolation yields a peak plasma concentration of 16 ng/mL for the 15 mg patch.

The maximum level of plasma concentration after administration is reached after approximately 9 hours (t_{max}). The plasma peak is in the afternoon/ evening when the risk of relapse is highest.

The volume of distribution of nicotine is about 2 to 3 L/kg and the half-life approximately 3 hours. The major eliminating organ is the liver, and average plasma clearance is about 70 L/hour. The kidney and lung also metabolise nicotine. More than 20 metabolites of nicotine have been identified, all of which are believed to be less active than the parent compound.
Plasma protein binding of nicotine is less than 5%. Therefore, changes in nicotine binding from use of concomitant drugs or alterations of plasma proteins by disease states would not be expected to have significant effects on nicotine kinetics.

The primary metabolite of nicotine in plasma, cotinine, has a half-life of 15 to 20 hours and concentrations that exceed nicotine by 10-fold.
The primary urinary metabolites are cotinine (12% of the dose) and trans-3-hydroxy-cotinine (37% of the dose). About 10% of nicotine is excreted unchanged in the urine.

Progressive severity of renal impairment is associated with decreased total clearance of nicotine. Raised nicotine levels have been seen in smoking patients undergoing haemodialysis.

The pharmacokinetics of nicotine is unaffected in cirrhotic patients with mild liver impairment (Child score 5) and nicotine clearance is decreased in cirrhotic patients with moderate liver impairment (Child score 7).

A minor reduction in total clearance of nicotine has been demonstrated in healthy elderly patients, however, not justifying adjustment of dosage.
Plasma nicotine concentrations show dose proportionality for the three patch doses.

5.3 Preclinical safety data

Preclinical data indicate that nicotine is neither mutagenic nor genotoxic. There are no other findings derived from preclinical testing of relevance to the prescriber in determining the safety of the product which have not been

considered in other relevant sections of this Summary of Product Characteristics.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Triglycerides, medium-chain
basic butylated methacrylate copolymer
Polyethylenterephthalate film (PET)

Acrylate Matrix
Acrylic adhesive solution
Potassium hydroxide
Croscarmellose sodium
Aluminium acetylacetonate

Release Liner
Polyethylenterephthalate (PET) film single side aluminised, both sides siliconised

Printing Ink Solution
Blending varnish
Printing ink brown

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

36 months.

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container

Package sizes: 10 mg/16 h 7 and 14 patches

All pack sizes may not be marketed.

Each patch is packed in a heat-sealed laminate pouch consisting of paper, PET film, aluminium acrylnitrilcopolymer or cyclo olefine copolymer coextrudate.

6.6 Special precautions for disposal

Nicotine residues in the used patches may present a hazard to children and pets, thus used patches should be folded, sticky sides together, put back in an empty pouch and placed in household rubbish.

7 MARKETING AUTHORISATION HOLDER

McNeil Products Limited
1 Station Hill Square
Station Hill
Reading
RG1 1LN
UK

8 MARKETING AUTHORISATION NUMBER(S)

PL 15513/0159

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

02/12/2008 / 09/10/2024

10 DATE OF REVISION OF THE TEXT

29 April 2026

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Nicorette Invisi 15 mg Patch
NicAssist Translucent 15 mg Patch.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each patch is 13.5 sq.cm, containing nicotine 1.75mg/sq.cm, releasing a nominal 15 mg of nicotine per 16 hours.

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Transdermal patch.

Semi-transparent, beige, imprinted 13.5 cm^2 rectangular TTS with rounded corners. Centrally located on a rectangular, aluminized and siliconised release liner'.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Nicorette Invisi Patch relieves and/or prevents craving and nicotine withdrawal symptoms in nicotine dependence, such as those arising from the use of tobacco or electronic cigarettes. It is indicated to aid quitting or reduction prior to quitting, to assist those who are unwilling or unable to use such products, and as a safer alternative to smoking tobacco for smokers and those around them.

Nicorette Invisi Patch is indicated in pregnant and lactating women making a quit attempt (see section 4.6).

4.2 Posology and method of administration

When making a quit attempt behavioural therapy, advice and support will normally improve the success rate.

It is intended that the patch is worn through the waking hours (approximately 16 hours) being applied on waking and removed at bedtime.

Smoking/Vaping Cessation

Adults (over 18 years of age)
For best results, most smokers/vapers are recommended to start on 25 mg / 16 hours patch (Step 1) and use one patch daily for 8 weeks. Gradual weaning from the patch should then be initiated. One 15 mg/16 hours patch (Step 2) should be used daily for 2 weeks followed by one 10 mg/16 hours patch (Step 3) daily for 2 weeks.

	Dose	Duration
Step 1	Nicorette Invisi 25 mg Patch	First 8 weeks
Step 2	Nicorette Invisi 15 mg Patch	Next 2 weeks
Step 3	Nicorette Invisi 10 mg Patch	Last 2 weeks

Lighter smokers (i.e. those who smoke less than 10 cigarettes per day) and light to moderate vapers (e.g. vape infrequently or use low strength e-liquid) are recommended to start at Step 2 (15 mg) for 8 weeks and decrease the dose to 10 mg for the final 4 weeks.

Those who experience excessive side effects with the 25 mg / 16 hours patch (Step 1), which do not resolve within a few days, should change to a 15 mg / 16 hours patch (Step 2). This should be continued for the remainder of the 8 week course, before stepping down to the 10 mg / 16 hours patch (Step 3) for 4 weeks. If symptoms persist the advice of a healthcare professional should be sought.

Adolescents (12 to 18 years)
The dose and method of use are as for adults however as data are limited in this age group, the recommended treatment duration is 12 weeks. If longer treatment is required, advice from a healthcare professional should be sought.

Smoking/Vaping Reduction/Pre-Quit
Smokers/vapers are recommended to use the patch to prolong smoke/vape-free intervals and with the intention to reduce smoking/vaping as much as possible.

The starting dose should follow the smoking/vaping cessation instructions above i.e. 25 mg (Step 1) is suitable for those who smoke 10 or more cigarettes per day or heavy vapers (e.g. vape frequently or use high strength e-liquid). Lighter smokers (i.e. those who smoke less than 10 cigarettes per day) and light to moderate vapers (e.g. vape infrequently or use low strength e-liquid) are recommended to start at Step 2 (15 mg).

Smokers/vapers starting on 25 mg patch (Step 1) should transfer to 15 mg patch (Step 2) as soon as cigarette consumption reduces to less than 10 cigarettes per day or vaping dependency decreases.

A quit attempt should be made as soon as the smoker/vaper feels ready. When making a quit attempt patients who have reduced to less than 10 cigarettes per day are recommended to continue at Step 2 (15 mg) for 8 weeks and decrease the dose to 10 mg (Step 3) for the final 4 weeks. When vapers have reduced their dependency sufficiently (e.g. vape infrequently or use low strength e-liquid), they should continue at Step 2 (15 mg) for 8 weeks and then step down to 10 mg (Step 3) for the final 4 weeks.

Temporary Abstinence
Use a Nicorette Invisi Patch in those situations when you can't or do not want to smoke/vape for prolonged periods (greater than 16 hours).

For shorter periods then an alternative intermittent dose form would be more suitable (e.g. Nicorette inhalator or gum).

Smokers of 10 or more cigarettes per day or heavy vapers (e.g. vape frequently or use high-strength e-liquid) are recommended to use 25 mg patch. Lighter smokers (i.e. those who smoke less than 10 cigarettes per day) and light to moderate vapers (e.g. vape infrequently or use low strength e-liquid) are recommended to use 15 mg patch.

How to apply the patches
Nicorette Invisi Patch should be applied to clean, dry intact areas of hairless skin, for example on the hip, upper arm, or chest. These areas should be varied each day, and the same site should not be used on consecutive days.

1. Wash your hands before applying the patch.
2. Cut open the pouch with scissors along the side, as indicated. Select a clean, dry, hairless intact area of skin, such as the hip, upper arm or chest.
3. Peel one part of the silvery aluminium backing away. Avoid touching the sticky surface of the patch with your fingers.
4. Apply the sticky part of the patch carefully onto the skin and peel off the remaining half of the silvery aluminium backing.
5. Press the patch firmly onto the skin with your palm or fingertips.
6. Rub your fingers firmly round the edge to ensure that the patch sticks firmly.

Use of skin oils or talc can prevent proper adhesion of the patch.

After removal, used patches should be disposed of carefully.

4.3 Contraindications

Nicorette Invisi Patches should not be administered to patients with known hypersensitivity to nicotine or any component of the patch.

4.4 Special warnings and precautions for use

Any risks that may be associated with NRT are substantially outweighed by the well-established dangers of continued smoking. The risks of continued vaping are not yet established.

A risk-benefit assessment should be made by an appropriate healthcare professional for patients with the following conditions:

Underlying cardiovascular disease: In stable cardiovascular disease this product presents a lesser hazard than continuing to smoke. However dependent smokers currently hospitalised as a result of myocardial infarction, unstable or worsening angina including Prinzmetal angina, severe dysrhythmia or CVA and who are considered to be haemodynamically unstable and/or who have uncontrolled hypertension should be encouraged to stop smoking with non-pharmacological interventions. If this fails, this product may be considered, but as data on safety in this patient group are limited, initiation should only be under medical supervision. The risks of continued vaping are not yet established.

Diabetes mellitus: Patients with diabetes mellitus should be advised to monitor their blood sugar levels more closely than usual when quitting and NRT is initiated as reductions in nicotine induced catecholamine release can affect carbohydrate metabolism.

Renal or hepatic impairment: This product should be used with caution in patients with moderate to severe hepatic impairment and/or severe renal impairment as the clearance of nicotine or its metabolites may be decreased with the potential for increased adverse effects.

Seizures: Potential risks and benefits of nicotine should be carefully evaluated before use in subjects with a history of epilepsy as cases of convulsions have been reported in association with nicotine.

Danger in children: Doses of nicotine tolerated by adult and adolescent smokers or vapers can produce severe toxicity in children that may be fatal. Products containing nicotine should not be left where they may be misused, handled or ingested by children. After removal, the patch should be folded in half, adhesive side innermost, and placed inside the opened sachet, or in a piece of aluminium foil. The used patch should then be disposed of carefully, away from the reach of children or animals.

Phaeochromocytoma and uncontrolled hyperthyroidism: As nicotine causes release of catecholamines, this product should be used with caution in patients with uncontrolled hyperthyroidism or phaeochromocytoma.

Transferred dependence: Transferred dependence is rare and is both less harmful and easier to break than smoking dependence.

Stopping smoking: Polycyclic aromatic hydrocarbons in tobacco smoke induce the metabolism of drugs metabolised by CYP 1A2 (and possibly by CYP 1A1). When a smoker stops smoking, this may result in slower metabolism and a consequent rise in blood levels of such drugs. This is of potential clinical importance for products with a narrow therapeutic window, e.g. theophylline, clozapine and ropinirole.

Gastrointestinal disease: Nicotine may exacerbate symptoms in patients suffering from oesophagitis, gastric or peptic ulcers and NRT preparations should be used with caution in these conditions.

Generalised dermatological disorders: Patients with chronic generalised dermatological disorders such as psoriasis, chronic dermatitis or urticaria should not use this product.

Angioedema and urticaria have been reported.
Erythema may occur. If it is severe or persistent, treatment should be discontinued.

Minor skin reactions are seen at the patch application site in a proportion of patients when commencing treatment (see also section 4.8). If skin reactions become more severe or more generalized, patients should be advised to discontinue use of patches and seek further medical help regarding nicotine replacement therapy.

This product should be removed prior to undergoing any Magnetic Resonance Imaging (MRI) procedures to prevent the risk of burns.

4.5 Interaction with other medicinal products and other forms of interaction

No clinically relevant interactions between nicotine replacement therapy and other drugs have definitely been established. However nicotine may possibly enhance the haemodynamic effects of adenosine i.e. increase in blood pressure and heart rate and also increase pain response (angina-pectoris type chest pain) provoked by adenosine administration.

4.6 Fertility, pregnancy and lactation

Pregnancy
Stopping smoking is the single most effective intervention for improving the health of both the pregnant smoker and her baby, and the earlier abstinence is achieved the better. Ideally smoking cessation during pregnancy should be achieved without NRT. Nicotine passes to the foetus and affects its breathing movements and circulation. The effect on the circulation is dose-dependent. However, if the mother cannot (or is considered unlikely to) quit without pharmacological support, NRT may be used as the risk to the foetus is lower than that expected with smoking tobacco. Stopping completely is by far the best option but if this is not achievable Nicorette Invisi Patch may be used in pregnancy as a safer alternative to smoking. Because of the potential for nicotine-free periods, intermittent dose forms are preferable, but patches may be considered as an alternative if there is significant nausea and/or vomiting. If patches are used they should, if possible, be removed at night when the foetus would not normally be exposed to nicotine.

There is no or limited data regarding the effect of vaping in pregnancy.

Use of NRT by the pregnant smoker/vaper should only be initiated after advice from a health care professional.

Lactation
Nicotine should be avoided during breast-feeding. The relatively small amounts of nicotine found in breast milk during NRT use are less hazardous to the infant than second-hand smoke. Intermittent dose forms would minimize the amount of nicotine in breast milk and permit feeding when levels were at their lowest.

There is no or limited data regarding the effect of vaping in lactating women.

Use of NRT by breast feeding smokers/vapers should only be initiated after advice from a health care professional.

Fertility
In females tobacco smoking delays time to conception, decreases in-vitro fertilization success rates, and significantly increases the risk of infertility.

In males tobacco smoking reduces sperm production, increases oxidative stress, and DNA damage. Spermatozoa from smokers have reduced fertilizing capacity.

The specific contribution of nicotine to these effects in humans is unknown.

There is no or limited data regarding the effect of vaping on fertility.

4.7 Effects on ability to drive and use machines

This product has no or negligible influence on the ability to drive and use machines.

4.8 Undesirable effects

Effect of Smoking Cessation
Some symptoms may be related to nicotine withdrawal associated with stopping smoking. These can include irritability/aggression, dysphoria/depressed mood, anxiety, restlessness, poor concentration, increased appetite/weight gain, urges to smoke (cravings), night-time awakenings/sleep disturbance, decreased heart rate, dizziness, presyncopal symptoms, cough, constipation, gingival bleeding or nasopharyngitis. Increased frequency of aphthous ulcer may occur after abstinence from smoking. The causality is unclear.

Effect of Vaping Cessation
The nicotine withdrawal effects of vaping cessation have not been established; however it is anticipated that many of the effects relating to nicotine withdrawal will be the same as those seen with tobacco smoking cessation.

Adverse Drug Reactions (ADRs)
This product may cause adverse reactions similar to those associated with nicotine given by other means, including smoking and vaping, and these are mainly dose-dependent. At recommended doses this product has not been

found to cause any serious adverse effects. Excessive use of this product by those who have not been in the habit of inhaling tobacco smoke or vaping could possibly lead to nausea, faintness or headaches.

Most of the undesirable effects reported by the subjects occur during the early phase of treatment and are mainly dose dependent.

About 20% of Nicorette Invisi Patch users experience mild local skin reactions, during the first weeks of treatment. In some patients the skin reactions may become more severe e.g. skin blistering or a burning sensation or may be more generalized (see section 4.4).

Allergic reactions (including symptoms of anaphylaxis) occur rarely during use of this product.

Adverse events observed in patients treated with nicotine patch formulations during clinical trials and post-marketing surveillance are listed below by system organ class (SOC).

*Frequencies are defined in accordance with current guidance, as: *very common (≥1/10); common (≥1/100, <1/10); uncommon (≥1/1 000, <1/100); rare (≥1/10 000, <1/1 000); very rare (<1/10 000), not known - cannot be estimated from the available data. ** Frequency category estimated using the "Rule of 3"

Body System	**Reported adverse event (Preferred Term)**	**Incidence***
Immune system disorders	Hypersensitivity[a#]	Uncommon
	Anaphylactic reaction[a]	Rare**
Nervous system disorders	Dizziness Headache[a§]	Common
	Paraesthesia[a#]	Uncommon
	Seizures	Not known
Cardiac disorders	Palpitations[a] Tachycardia[a]	Uncommon
	Reversible atrial fibrillation	Very rare
Vascular disorders	Flushing[a] Hypertension[a]	Uncommon

Body System	Reported adverse event (Preferred Term)	Incidence*
Respiratory, Thoracic and Mediastinal Disorders	Dyspnoea[a]	Uncommon
Gastrointestinal disorders	Nausea[a§] Vomiting[a]	Common
	Gastrointestinal discomfort[a]	Rare**
Skin and subcutaneous tissue disorders	Pruritus	Very common
	Rash[a] Urticaria[a]	Common
	Hyperhidrosis[a]	Uncommon
	Angioedema[a] Erythema[a]	Rare**
Musculoskeletal and Connective Tissue Disorders	Myalgia[b]	Uncommon
	Pain in extremity	Rare**
General disorders and administration site conditions	Application site reactions Asthenia[a] Chest discomfort and pain[a] Malaise[a] Fatigue[a#§]	Uncommon

[a] Systemic effects; [b] In vicinity/region of patch
[#] Although the frequency is <1% the PT occurred at a frequency ≥1% in another formulation in which the PT was identified as a systemic ADR.
[§] Although the frequency in the active group is less than that of the placebo group, the frequency in the specific formulation in which the PT was identified as a systemic ADR was greater in the active group than the placebo group.

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the Yellow Card Scheme at:

www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

4.9 Overdose

Symptoms: Symptoms of overdose with nicotine from this product may occur in smokers/vapers who have previously had a low nicotine intake from cigarettes/e-cigarettes or if other sources of nicotine are used concomitantly with this product.

Acute or chronic toxicity of nicotine in man is highly dependent on mode and route of administration. Adaptation to nicotine (e.g. in smokers/vapers) is known to significantly increase tolerability compared with non-smokers/vapers.

The minimum lethal dose of nicotine in a non-tolerant man has been estimated to be 40 to 60 mg. Symptoms of acute nicotine poisoning include nausea, vomiting, increased salivation, abdominal pain, diarrhoea, sweating, headache, dizziness, disturbed hearing and marked weakness. In extreme cases, these symptoms may be followed by hypotension, rapid or weak or irregular pulse, breathing difficulties, prostration, circulatory collapse and terminal convulsions.

Management of an overdose: All nicotine intake should stop immediately and the patient should be treated symptomatically. Remove the patch and rinse the application site with water. Artificial respiration should be instituted if necessary. Activated charcoal reduces the gastro-intestinal absorption of nicotine.

Doses of nicotine that are tolerated by adult smokers/vapers during treatment may produce severe symptoms of poisoning in children and may prove fatal. Suspected nicotine poisoning in a child should be considered a medical emergency and treated immediately.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Drug used in nicotine dependence.
ATC code: N07B A01

Nicotine has no therapeutic uses except as replacement therapy for the relief of abstinence symptoms in nicotine-dependent smokers/vapers.

Owing to its many actions, the overall effects of nicotine are complex. A wide variety of stimulant and depressant effects are observed that involve the central and peripheral nervous, cardiovascular, endocrine, gastro-intestinal and skeletal motor systems. Nicotine acts on specific binding sites or receptors throughout the nervous system.

Increased appetite is a recognised symptom of nicotine withdrawal and post-cessation weight gain is common. Clinical trials have demonstrated that Nicotine Replacement Therapy can help control weight following a quit attempt.

5.2 Pharmacokinetic properties

The patches are labelled by the average amount of nicotine released over 16 hours.

A linear relationship exists between released amount of nicotine (dose) and plasma levels of nicotine over the therapeutic dose range, 10-25 mg/16 hours The mean peak plasma levels of nicotine (C_{max}) achieved are calculated to:

Dose nicotine (mg/16 hours)	C_{max} (ng/ml)
10	10
15	15.5
25	26.5

The calculated peak plasma levels are in the same range as true measured peak plasma concentrations: 11 ng/mL for the 10 mg patch and 25 ng/mL for the 25 mg patch. Interpolation yields a peak plasma concentration of 16 ng/m for the 15 mg patch.

The maximum level of plasma concentration after administration is reached after approximately 9 hours (t_{max}). The plasma peak is in the afternoon/ evening when the risk of relapse is highest.

The volume of distribution of nicotine is about 2 to 3 L/kg and the half-life approximately 3 hours. The major eliminating organ is the liver, and average plasma clearance is about 70 L/hour. The kidney and lung also metabolise nicotine. More than 20 metabolites of nicotine have been identified, all of which are believed to be less active than the parent compound.

Plasma protein binding of nicotine is less than 5%. Therefore, changes in nicotine binding from use of concomitant drugs or alterations of plasma proteins by disease states would not be expected to have significant effects on nicotine kinetics.

The primary metabolite of nicotine in plasma, cotinine, has a half-life of 15 to 20 hours and concentrations that exceed nicotine by 10-fold.
The primary urinary metabolites are cotinine (12% of the dose) and trans-3-hydroxy-cotinine (37% of the dose). About 10% of nicotine is excreted unchanged in the urine.

Progressive severity of renal impairment is associated with decreased total clearance of nicotine. Raised nicotine levels have been seen in smoking patients undergoing haemodialysis.

The pharmacokinetics of nicotine is unaffected in cirrhotic patients with mild liver impairment (Child score 5) and nicotine clearance is decreased in cirrhotic patients with moderate liver impairment (Child score 7).

A minor reduction in total clearance of nicotine has been demonstrated in healthy elderly patients, however, not justifying adjustment of dosage.

Plasma nicotine concentrations show dose proportionality for the three patch doses.

5.3 Preclinical safety data

Preclinical data indicate that nicotine is neither mutagenic nor genotoxic. There are no other findings derived from preclinical testing of relevance to the prescriber in determining the safety of the product which have not been considered in other relevant sections of this Summary of Product Characteristics.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Triglycerides, medium-chain
basic butylated methacrylate copolymer
Polyethylenterephthalate film (PET)

Acrylate Matrix
Acrylic adhesive solution
Potassium hydroxide
Croscarmellose sodium
Aluminium acetylacetonate

Release Liner
Polyethylenterephthalate (PET) film single side aluminised, both sides siliconised

Printing Ink Solution
Blending varnish
Printing ink brown

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

36 months.

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container

Package sizes: 15 mg/16 h 7 and 14 patches

All pack sizes may not be marketed.

Each patch is packed in a heat-sealed laminate pouch consisting of paper, PET film, aluminium acrylnitrilcopolymer or cyclo olefine copolymer coextrudate.

6.6 Special precautions for disposal

Nicotine residues in the used patches may present a hazard to children and pets, thus used patches should be folded, sticky sides together, put back in an empty pouch and placed in household rubbish.

7 MARKETING AUTHORISATION HOLDER

McNeil Products Limited
1 Station Hill Square
Station Hill
Reading
RG1 1LN
UK

8 MARKETING AUTHORISATION NUMBER(S)

PL 15513/0160

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

02/12/2008 / 09/10/2024

10 DATE OF REVISION OF THE TEXT

29 April 2026

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Nicorette Invisi 25 mg Patch
NicAssist Translucent 25 mg Patch.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each patch is 22.5 sq.cm, containing nicotine 1.75 mg/sq.cm, releasing a nominal 25 mg of nicotine per 16 hours.

For a full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Transdermal patch.

Semi-transparent, beige, imprinted 22.5 cm^2 rectangular TTS with rounded corners. Centrally located on a rectangular, aluminized and siliconised release liner.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Nicorette Invisi Patch relieves and/or prevents craving and nicotine withdrawal symptoms in nicotine dependence, such as those arising from the use of tobacco or electronic cigarettes. It is indicated to aid quitting or reduction prior to quitting, to assist those who are unwilling or unable to use such products, and as a safer alternative to smoking tobacco for smokers and those around them.

Nicorette Invisi Patch is indicated in pregnant and lactating women making a quit attempt (see section 4.6).

4.2 Posology and method of administration

When making a quit attempt behavioural therapy, advice and support will normally improve the success rate.

It is intended that the patch is worn through the waking hours (approximately 16 hours) being applied on waking and removed at bedtime.

Smoking/Vaping Cessation

Adults (over 18 years of age)
For best results, most smokers/vapers are recommended to start on 25 mg / 16 hours patch (Step 1) and use one patch daily for 8 weeks. Gradual weaning

from the patch should then be initiated. One 15 mg/16 hours patch (Step 2) should be used daily for 2 weeks followed by one 10 mg/16 hours patch (Step 3) daily for 2 weeks.

	Dose	Duration
Step 1	Nicorette Invisi 25 mg Patch	First 8 weeks
Step 2	Nicorette Invisi 15 mg Patch	Next 2 weeks
Step 3	Nicorette Invisi 10 mg Patch	Last 2 weeks

Lighter smokers (i.e. those who smoke less than 10 cigarettes per day) and light to moderate vapers (e.g. vape infrequently or use low strength e-liquid) are recommended to start at Step 2 (15 mg) for 8 weeks and decrease the dose to 10 mg for the final 4 weeks.

Those who experience excessive side effects with the 25 mg / 16 hours patch (Step 1), which do not resolve within a few days, should change to a 15mg / 16 hours patch (Step 2). This should be continued for the remainder of the 8 week course, before stepping down to the 10 mg / 16 hours patch (Step 3) for 4 weeks. If symptoms persist the advice of a healthcare professional should be sought.

Adolescents (12 to 18 years)
The dose and method of use are as for adults however as data are limited in this age group, the recommended treatment duration is 12 weeks. If longer treatment is required, advice from a healthcare professional should be sought.

Smoking/Vaping Reduction/Pre-Quit
Smokers/vapers are recommended to use the patch to prolong smoke/vape-free intervals and with the intention to reduce smoking/vaping as much as possible.

The starting dose should follow the smoking/vaping cessation instructions above i.e. 25 mg (Step 1) is suitable for those who smoke 10 or more cigarettes per day or heavy vapers (e.g. vape frequently or use high strength e-liquid). Lighter smokers (i.e. those who smoke less than 10 cigarettes per day) and light to moderate vapers (e.g. vape infrequently or use low strength e-liquid) are recommended to start at Step 2 (15 mg).

Smokers/vapers starting on 25 mg patch (Step 1) should transfer to 15 mg patch (Step 2) as soon as cigarette consumption reduces to less than 10 cigarettes per day or vaping dependency decreases.

A quit attempt should be made as soon as the smoker/vaper feels ready. When making a quit attempt patients who have reduced to less than 10 cigarettes per day are recommended to continue at Step 2 (15 mg) for 8 weeks and decrease the dose to 10 mg (Step 3) for the final 4 weeks. When vapers have reduced their dependency sufficiently (e.g. vape infrequently or use low strength e-

liquid), they should continue at Step 2 (15 mg) for 8 weeks and then step down to 10 mg (Step 3) for the final 4 weeks.

Temporary Abstinence
Use a Nicorette Invisi Patch in those situations when you can't or do not want to smoke/vape for prolonged periods (greater than 16 hours).

For shorter periods then an alternative intermittent dose form would be more suitable (e.g. Nicorette inhalator or gum).

Smokers of 10 or more cigarettes per day or heavy vapers (e.g. vape frequently or use high strength e-liquid) are recommended to use 25 mg patch. Lighter smokers (i.e. those who smoke less than 10 cigarettes per day) and light to moderate vapers (e.g. vape infrequently or use low strength e-liquid), are recommended to use 15 mg patch.

How to apply the patches
Nicorette Invisi Patch should be applied to clean, dry intact areas of hairless skin, for example on the hip, upper arm, or chest. These areas should be varied each day and the same site should not be used on consecutive days.

1. Wash your hands before applying the patch.
2. Cut open the pouch with scissors along the side, as indicated. Select a clean, dry, hairless intact area of skin, such as the hip, upper arm or chest.
3. Peel one part of the silvery aluminium backing away. Avoid touching the sticky surface of the patch with your fingers.
4. Apply the sticky part of the patch carefully onto the skin and peel off the remaining half of the silvery aluminium backing.
5. Press the patch firmly onto the skin with your palm or fingertips.
6. Rub your fingers firmly round the edge to ensure that the patch sticks firmly.

Use of skin oils or talc can prevent proper adhesion of the patch.

After removal, used patches should be disposed of carefully.

4.3 Contraindications

Nicorette Invisi Patches should not be administered to patients with known hypersensitivity to nicotine or any component of the patch.

4.4 Special warnings and precautions for use

Any risks that may be associated with NRT are substantially outweighed by the well-established dangers of continued smoking. The risks of continued vaping are not yet established.

A risk-benefit assessment should be made by an appropriate healthcare professional for patients with the following conditions:

Underlying cardiovascular disease: In stable cardiovascular disease this product presents a lesser hazard than continuing to smoke. However

dependent smokers currently hospitalised as a result of myocardial infarction, unstable or worsening angina including Prinzmetal angina, severe dysrhythmia or CVA and who are considered to be haemodynamically unstable and/or who have uncontrolled hypertension should be encouraged to stop smoking with non-pharmacological interventions. If this fails, this product may be considered, but as data on safety in this patient group are limited, initiation should only be under medical supervision. The risks of continued vaping are not yet established.

Diabetes mellitus: Patients with diabetes mellitus should be advised to monitor their blood sugar levels more closely than usual when quitting and NRT is initiated as reductions in nicotine induced catecholamine release can affect carbohydrate metabolism.

Renal or hepatic impairment: This product should be used with caution in patients with moderate to severe hepatic impairment and/or severe renal impairment as the clearance of nicotine or its metabolites may be decreased with the potential for increased adverse effects.

Seizures: Potential risks and benefits of nicotine should be carefully evaluated before use in subjects with a history of epilepsy as cases of convulsions have been reported in association with nicotine.

Danger in children: Doses of nicotine tolerated by adult and adolescent smokers or vapers can produce severe toxicity in children that may be fatal. Products containing nicotine should not be left where they may be misused, handled or ingested by children. After removal, the patch should be folded in half, adhesive side innermost, and placed inside the opened sachet, or in a piece of aluminium foil. The used patch should then be disposed of carefully, away from the reach of children or animals.

Phaeochromocytoma and uncontrolled hyperthyroidism: As nicotine causes release of catecholamines, this product should be used with caution in patients with uncontrolled hyperthyroidism or phaeochromocytoma.

Transferred dependence: Transferred dependence is rare and is both less harmful and easier to break than smoking dependence.

Stopping smoking: Polycyclic aromatic hydrocarbons in tobacco smoke induce the metabolism of drugs metabolised by CYP 1A2 (and possibly by CYP 1A1). When a smoker stops smoking, this may result in slower metabolism and a consequent rise in blood levels of such drugs. This is of potential clinical importance for products with a narrow therapeutic window, e.g. theophylline, clozapine and ropinirole.

Gastrointestinal disease: Nicotine may exacerbate symptoms in patients suffering from oesophagitis, gastric or peptic ulcers and NRT preparations should be used with caution in these conditions.

Generalised dermatological disorders: Patients with chronic generalised dermatological disorders such as psoriasis, chronic dermatitis or urticaria should not use this product.

Angioedema and urticaria have been reported.
Erythema may occur. If it is severe or persistent, treatment should be discontinued.

Minor skin reactions are seen at the patch application site in a proportion of patients when commencing treatment (see also section 4.8). If skin reactions become more severe or more generalized, patients should be advised to discontinue use of patches and seek further medical help regarding nicotine replacement therapy.

This product should be removed prior to undergoing any Magnetic Resonance Imaging (MRI) procedures to prevent the risk of burns.

4.5 Interaction with other medicinal products and other forms of interaction

No clinically relevant interactions between nicotine replacement therapy and other drugs have definitely been established. However nicotine may possibly enhance the haemodynamic effects of adenosine i.e. increase in blood pressure and heart rate and also increase pain response (angina-pectoris type chest pain) provoked by adenosine administration.

4.6 Fertility, pregnancy and lactation

Pregnancy
Stopping smoking is the single most effective intervention for improving the health of both the pregnant smoker and her baby, and the earlier abstinence is achieved the better. Ideally smoking cessation during pregnancy should be achieved without NRT. Nicotine passes to the foetus and affects its breathing movements and circulation. The effect on the circulation is dose-dependent. However, if the mother cannot (or is considered unlikely to) quit without pharmacological support, NRT may be used as the risk to the foetus is lower than that expected with smoking tobacco. Stopping completely is by far the best option but if this is not achievable Nicorette Invisi Patch may be used in pregnancy as a safer alternative to smoking. Because of the potential for nicotine-free periods, intermittent dose forms are preferable, but patches may be considered as an alternative if there is significant nausea and/or vomiting. If patches are used they should, if possible, be removed at night when the foetus would not normally be exposed to nicotine.

There is no or limited data regarding the effect of vaping in pregnancy.

Use of NRT by the pregnant smoker/vaper should only be initiated after advice from a health care professional.

Lactation
Nicotine should be avoided during breast-feeding. The relatively small amounts of nicotine found in breast milk during NRT use are less hazardous to

the infant than second-hand smoke. Intermittent dose forms would minimize the amount of nicotine in breast milk and permit feeding when levels were at their lowest.

There is no or limited data regarding the effect of vaping in lactating women.

Use of NRT by breast feeding smokers/vapers should only be initiated after advice from a health care professional.

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The specific contribution of nicotine to these effects in humans is unknown.

There is no or limited data regarding the effect of vaping on fertility.

4.7 Effects on ability to drive and use machines

This product has no or negligible influence on the ability to drive and use machines.

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Some symptoms may be related to nicotine withdrawal associated with stopping smoking. These can include irritability/aggression, dysphoria/depressed mood, anxiety, restlessness, poor concentration, increased appetite/weight gain, urges to smoke (cravings), night-time awakenings/sleep disturbance, decreased heart rate, dizziness, presyncopal symptoms, cough, constipation, gingival bleeding or nasopharyngitis. Increased frequency of aphthous ulcer may occur after abstinence from smoking. The causality is unclear.

Effects of Vaping Cessation
The nicotine withdrawal effects of vaping cessation have not been established; however it is anticipated that many of the effects relating to nicotine withdrawal will be the same as those seen with tobacco smoking cessation.

Adverse Drug Reactions (ADRs)
This product may cause adverse reactions similar to those associated with nicotine given by other means, including smoking and vaping, and these are mainly dose-dependent. At recommended doses this product has not been found to cause any serious adverse effects. Excessive use of this product by those who have not been in the habit of inhaling tobacco smoke or vaping could possibly lead to nausea, faintness or headaches.

Most of the undesirable effects reported by the subjects occur during the early phase of treatment and are mainly dose dependent.

About 20% of Nicorette Invisi Patch users experience mild local skin reactions, during the first weeks of treatment. In some patients the skin reactions may become more severe e.g. skin blistering or a burning sensation or may be more generalized (see section 4.4).

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Adverse events observed in patients treated with nicotine patch formulations during clinical trials and post-marketing surveillance are listed below by system organ class (SOC).

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	Seizures	Not known
Cardiac disorders	Palpitations[a] Tachycardia[a]	Uncommon
	Reversible atrial fibrillation	Very rare
Vascular disorders	Flushing[a] Hypertension[a]	Uncommon
Respiratory, Thoracic and Mediastinal Disorders	Dyspnoea[a]	Uncommon

Body System	Reported adverse event (Preferred Term)	Incidence*
Gastrointestinal disorders	Nausea[a§] Vomiting[a]	Common
	Gastrointestinal discomfort[a]	Rare**
Skin and subcutaneous tissue disorders	Pruritus	Very common
	Rash[a] Urticaria[a]	Common
	Hyperhidrosis[a]	Uncommon
	Angioedema[a] Erythema[a]	Rare**
Musculoskeletal and Connective Tissue Disorders	Myalgia[b]	Uncommon
	Pain in extremity	Rare**
General disorders and administration site conditions	Application site reactions Asthenia[a] Chest discomfort and pain[a] Malais[a] Fatigue[a#§]	Uncommon

[a] Systemic effects; [b] In vicinity/region of patch

[#] Although the frequency is <1% the PT occurred at a frequency ≥1% in another formulation in which the PT was identified as a systemic ADR.

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Acute or chronic toxicity of nicotine in man is highly dependent on mode and route of administration. Adaptation to nicotine (e.g. in smokers/vapers) is known to significantly increase tolerability compared with non-smokers/vapers.

The minimum lethal dose of nicotine in a non-tolerant man has been estimated to be 40 to 60 mg. Symptoms of acute nicotine poisoning include nausea, vomiting, increased salivation, abdominal pain, diarrhoea, sweating, headache, dizziness, disturbed hearing and marked weakness. In extreme cases, these symptoms may be followed by hypotension, rapid or weak or irregular pulse, breathing difficulties, prostration, circulatory collapse and terminal convulsions.

Management of an overdose: All nicotine intake should stop immediately and the patient should be treated symptomatically. Remove the patch and rinse the application site with water. Artificial respiration should be instituted if necessary. Activated charcoal reduces the gastro-intestinal absorption of nicotine.

Doses of nicotine that are tolerated by adult smokers/vapers during treatment may produce severe symptoms of poisoning in children and may prove fatal. Suspected nicotine poisoning in a child should be considered a medical emergency and treated immediately.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Drug used in nicotine dependence.
ATC code: N07B A01

Nicotine has no therapeutic uses except as replacement therapy for the relief of abstinence symptoms in nicotine-dependent smokers/vapers.

Owing to its many actions, the overall effects of nicotine are complex. A wide variety of stimulant and depressant effects are observed that involve the central and peripheral nervous, cardiovascular, endocrine, gastro-intestinal and skeletal motor systems. Nicotine acts on specific binding sites or receptors throughout the nervous system.

Increased appetite is a recognised symptom of nicotine withdrawal and post-cessation weight gain is common. Clinical trials have demonstrated that

Nicotine Replacement Therapy can help control weight following a quit attempt.

5.2 Pharmacokinetic properties

The patches are labelled by the average amount of nicotine released over 16 hours.

A linear relationship exists between released amount of nicotine (dose) and plasma levels of nicotine over the therapeutic dose range, 10-25 mg/16 hours. The mean peak plasma levels of nicotine (C_{max}) achieved are calculated to:

Dose nicotine (mg/16 hours)	C_{max} (ng/ml)
10	10
15	15.5
25	26.5

The calculated peak plasma levels are in the same range as true measured peak plasma concentrations: 11 ng/mL for the 10 mg patch and 25 ng/mL for the 25 mg patch. Interpolation yields a peak plasma concentration of 16 ng/mL for the 15 mg patch.

The maximum level of plasma concentration after administration is reached after approximately 9 hours (t_{max}). The plasma peak is in the afternoon/ evening when the risk of relapse is highest.

The volume of distribution of nicotine is about 2 to 3 L/kg and the half-life approximately 3 hours. The major eliminating organ is the liver, and average plasma clearance is about 70 L/hour. The kidney and lung also metabolise nicotine. More than 20 metabolites of nicotine have been identified, all of which are believed to be less active than the parent compound.

Plasma protein binding of nicotine is less than 5%. Therefore, changes in nicotine binding from use of concomitant drugs or alterations of plasma proteins by disease states would not be expected to have significant effects on nicotine kinetics.

The primary metabolite of nicotine in plasma, cotinine, has a half-life of 15 to 20 hours and concentrations that exceed nicotine by 10-fold.
The primary urinary metabolites are cotinine (12% of the dose) and trans-3-hydroxy-cotinine (37% of the dose). About 10% of nicotine is excreted unchanged in the urine.

Progressive severity of renal impairment is associated with decreased total clearance of nicotine. Raised nicotine levels have been seen in smoking patients undergoing haemodialysis.

The pharmacokinetics of nicotine is unaffected in cirrhotic patients with mild liver impairment (Child score 5) and nicotine clearance is decreased in cirrhotic patients with moderate liver impairment (Child score 7).

A minor reduction in total clearance of nicotine has been demonstrated in healthy elderly patients, however, not justifying adjustment of dosage. Plasma nicotine concentrations show dose proportionality for the three patch doses.

5.3 Preclinical safety data

Preclinical data indicate that nicotine is neither mutagenic nor genotoxic. There are no other findings derived from preclinical testing of relevance to the prescriber in determining the safety of the product which have not been considered in other relevant sections of this Summary of Product Characteristics.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Triglycerides, medium-chain
basic butylated methacrylate copolymer
Polyethylenterephthalate film (PET)

Acrylate Matrix
Acrylic adhesive solution
Potassium hydroxide
Croscarmellose sodium
Aluminium acetylacetonate

Release Liner
Polyethylenterephthalate (PET) film single side aluminised, both sides siliconised

Printing Ink Solution
Blending varnish
Printing ink brown

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

36 months.

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container

Package sizes: 25 mg/16 h 2, 7 and 14 patches.

All pack sizes may not be marketed.

Each patch is packed in a heat-sealed laminate pouch consisting of paper, PET film, aluminium acrylnitrilcopolymer or cyclo olefine copolymer coextrudate.

6.6 Special precautions for disposal

Nicotine residues in the used patches may present a hazard to children and pets, thus used patches should be folded, sticky sides together, put back in an empty pouch and placed in household rubbish.

7 MARKETING AUTHORISATION HOLDER

McNeil Products Limited
1 Station Hill Square
Station Hill
Reading
RG1 1LN
UK

8 MARKETING AUTHORISATION NUMBER(S)

PL 15513/0161

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

02/12/2008 /09/10/2024

10 DATE OF REVISION OF THE TEXT

29 April 2026

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Nicorette QuickMist 1mg/spray mouthspray
Nicorette QuickMist SmartTrack 1mg/spray mouthspray

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

0.07 ml contains 1 mg nicotine, corresponding to 1 mg nicotine/spray dose.

Excipients with known effect:
Ethanol 7.1 mg/spray
Propylene glycol (E1520) 11 mg/spray
Butylated hydroxytoluene (E321) 363 ng/spray

For a full list of excipients see section 6.1.

3 PHARMACEUTICAL FORM

Oromucosal spray.
A clear to weakly opalescent, colourless to light yellow solution with a scent of peppermint.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Nicorette QuickMist relieves and/or prevents craving and nicotine withdrawal symptoms in nicotine dependence, such as those arising from the use of tobacco or electronic cigarettes. It is indicated to aid quitting or reduction prior to quitting, to assist those who are unwilling or unable to use such products, and as a safer alternative to smoking tobacco for smokers and those around them.

Nicorette QuickMist is indicated in pregnant and lactating women making a quit attempt.

4.2 Posology and method of administration

The patient should make every effort to stop smoking or vaping completely during treatment with Nicorette QuickMist.

Behavioural therapy, advice and support will normally improve the success rate.

Directions for use
For those using Nicorette QuickMist for the first time or those who have not used the spray for 2 days, they must first prime the spray pump.

Priming

1. Point the spray safely away from you and any other adults, children or pets that are near you.
2. Press the top of the QuickMist with your index finger 3 times until a fine spray appears.

   Note: priming reduces the number of sprays you may get from Nicorette QuickMist.
   After priming, point the spray nozzle as close to the open mouth as possible. Press the top of the dispenser and release one spray into your mouth, avoiding the lips. Do not inhale while spraying to avoid getting spray down your throat. For best results, do not swallow for a few seconds after spraying.
   The patient should not eat or drink when administering the oromucosal spray. Care should be taken not to spray the eyes whilst administering the mouth spray.

   Adults and Children over 12 years of age
   Use 1 or 2 sprays when you would normally have smoked or vaped or if cravings emerge. If after the first spray cravings are not controlled within a few minutes, a second spray should be used. If 2 sprays are required, future doses may be delivered as 2 consecutive sprays.
   Most smokers will require 1-2 sprays every 30 minutes to 1 hour.

   You may use up to 4 sprays per hour. Do not exceed 2 sprays per dosing episode and 64 sprays (4 sprays per hour over 16 hours) in any 24-hour period.

   Each mouthspray contains at least 150 sprays.

   Nicorette QuickMist should be used whenever the urge to smoke or vape is felt or to prevent cravings in situations where these are likely to occur.

   Patients willing or able to stop smoking/vaping immediately should initially replace all their cigarettes/e-cigarettes with the Nicorette QuickMist and as soon as they are able, reduce the number of sprays used until they have stopped completely.

   Patients aiming to reduce cigarettes/e-cigarettes should use the Mouthspray between smoking/vaping episodes, as needed, to prolong smoke/vape-free intervals and to reduce their use as much as possible.

   As soon as they are ready patients should aim to quit smoking/vaping completely.

   When making a quit attempt behavioural therapy, advice and support will normally improve the success rate. Those who have quit smoking/vaping but are having difficulty discontinuing their Mouthspray are recommended to contact their pharmacist or doctor for advice.

4.3 Contraindications

Hypersensitivity to the active substance or to any of the excipients of the mouthspray listed in section 6.1.

Nicorette QuickMist is contraindicated in children under 12 years.

4.4 Special warnings and precautions for use

Any risks that may be associated with NRT are substantially outweighed by the well-established dangers of continued smoking. The risks of continued vaping are not yet established.

A risk-benefit assessment should be made by an appropriate healthcare professional for patients with the following conditions:

Underlying cardiovascular disease: In stable cardiovascular disease this product presents a lesser hazard than continuing to smoke. However dependent smokers currently hospitalised as a result of myocardial infarction, unstable or worsening angina including Prinzmetal's angina, severe dysrhythmia or cerebrovascular accident and who are considered to be haemodynamically unstable and/or who have uncontrolled hypertension should be encouraged to stop smoking with non-pharmacological interventions. If this fails, this product may be considered, but as data on safety in this patient group are limited, initiation should only be under medical supervision. The risks of continued vaping are not yet established.

Diabetes mellitus: Patients with diabetes mellitus should be advised to monitor their blood sugar levels more closely than usual when quitting, and NRT is initiated as reductions in nicotine induced catecholamines released by nicotine can affect carbohydrate metabolism.

GI disease: Nicotine may exacerbate symptoms in patients suffering from oesophagitis, gastritis or peptic ulcers and NRT preparations should be used with caution in these conditions.

Renal or hepatic impairment: This product should be used with caution in patients with moderate to severe hepatic impairment and/or severe renal impairment as the clearance of nicotine or its metabolites may be decreased with the potential for increased adverse effects.

Seizures: Potential risks and benefits of nicotine should be carefully evaluated before use in subjects with a history of epilepsy as cases of convulsions have been reported in association with nicotine.

Danger in children: Doses of nicotine tolerated by adult and adolescent smokers or vapers can produce severe toxicity in children that may be fatal. Products containing nicotine should not be left where they may be misused, handled or ingested by children. See Section 4.9 Overdose.

Phaeochromocytoma and uncontrolled hyperthyroidism: As nicotine causes release of catecholamines, this product should be used with caution in patients with uncontrolled hyperthyroidism or phaeochromocytoma.

Transferred dependence: Transferred dependence is rare and is both less harmful and easier to break than smoking dependence.

Stopping smoking: Polycyclic aromatic hydrocarbons in tobacco smoke induce the metabolism of drugs metabolised by CYP 1A2 (and possibly by CYP 1A1). When a smoker stops smoking, this may result in slower metabolism and a consequent rise in blood levels of such drugs. This is of potential clinical importance for products with a narrow therapeutic window, e.g. theophylline, clozapine and ropinirole.

Excipients: This mouthspray contains about 7 mg of alcohol (ethanol) in each spray which is equivalent to 97 mg/ml. The amount in one spray of this medicine is equivalent to less than 2 ml beer or 1 ml wine. The small amount of alcohol in this medicine will not have any noticeable effects. This medicine contains 11 mg propylene glycol in each spray which is equivalent to 150 mg/mL. Due to the presence of a small amount of butylated hydroxytoluene (BHT), this medicine may cause local skin reactions (e.g. contact dermatitis), or irritation to the eyes and mucous membranes. This medicine contains less than 1 mmol sodium (23 mg) per spray, that is to say essentially 'sodium-free'.

Care should be taken not to spray the eyes whilst administering the spray.

4.5 Interaction with other medicinal products and other forms of interactions

No clinically relevant interactions between nicotine replacement therapy and other drugs have definitely been established. However nicotine may possibly enhance the haemodynamic effects of adenosine i.e. increase in blood pressure and heart rate and also increase pain response (angina-pectoris type chest pain) provoked by adenosine administration.

4.6 Fertility, pregnancy and lactation

Fertility

In females tobacco smoking delays time to conception, decreases in-vitro fertilization success rates, and significantly increases the risk of infertility.
In males tobacco smoking reduces sperm production, increases oxidative stress, and DNA damage. Spermatozoa from smokers have reduced fertilizing capacity.
The specific contribution of nicotine to these effects in humans is unknown.
There is no or limited data regarding the effect of vaping on fertility.

Pregnancy

Stopping smoking is the single most effective intervention for improving the health of both the pregnant smoker and her baby, and the earlier abstinence is achieved the better. Ideally smoking cessation during pregnancy should be achieved without NRT. Nicotine passes to the foetus and affects its breathing movements and circulation. The effect on the circulation is dose-dependent. However, if the mother cannot (or is considered unlikely to) quit without pharmacological support, NRT may be used as the risk to the fetus is lower than that expected with smoking tobacco. Stopping completely is by far the best option but if this is not achievable Nicorette QuickMist may be used in

pregnancy as a safer alternative to smoking. Because of the potential for nicotine-free periods, intermittent dose forms are preferable, but patches may be considered as an alternative if there is significant nausea and/or vomiting. If patches are used they should, if possible, be removed at night when the fetus would not normally be exposed to nicotine.

Use of nicotine by the pregnant smoker should only be initiated after advice from a health care professional.
There is no or limited data regarding the effect of vaping in pregnancy.

Lactation
Nicotine should be avoided during breast-feeding The relatively small amounts of nicotine found in breast milk during NRT use are less hazardous to the infant than second-hand smoke. Intermittent dose forms would minimize the amount of nicotine in breast milk and permit feeding when levels were at their lowest.
Use of the nicotine by breast feeding smokers should only be initiated after advice from a health care professional. Women should take the product as soon as possible after breastfeeding.

There is no or limited data regarding the effect of vaping in lactating women.

4.7 Effects on ability to drive and use machines

Nicorette QuickMist has no or negligible influence on the ability to drive and use machines.

4.8 Undesirable effects

Effects of smoking Cessation
Some symptoms may be related to nicotine withdrawal associated with stopping smoking. These can include the following: dysphoria or depressed mood; insomnia; irritability, frustration or anger; anxiety; difficulty concentrating, restlessness or impatience; decreased heart rate; and increased appetite or weight gain. These have been observed in those using the mouthspray.

Increased frequency of aphthous ulcer, cough and nasopharyngitis may occur after abstinence from smoking. The causality is unclear.

In addition to this, other cessation-associated symptoms were seen in those using the mouth spray: dizziness, presyncopal symptoms, constipation, and gingival bleeding.

Nicotine craving, which is recognised as a clinically relevant symptom, is an important element in nicotine withdrawal after smoking cessation.

Effects of vaping Cessation
The nicotine withdrawal effects of vaping cessation have not been established, however it is anticipated that many of the effects relating to nicotine withdrawal will be the same as those seen with tobacco smoking cessation.

Adverse Drug Reactions

This product may cause adverse reactions similar to those associated with nicotine given by other means, including smoking and vaping, and these are mainly dose-dependent.

Most adverse events reported with this product occur during the early phase of treatment and are similar to those seen with other orally delivered forms. During the first few days of treatment irritation to the mouth and throat may be experienced and hiccups are particularly common. Tolerance is normal with continued use.

Daily collection of data from trial subjects demonstrated that very commonly occurring adverse events were reported with onset in the first 2-3 weeks of use of the spray, and declined thereafter.

Allergic reactions (including symptoms of anaphylaxis) occur rarely during use of this product.

The adverse reactions observed in patients treated with oral nicotine formulations during clinical trials and post-marketing experience are listed below by System Organ Class (SOC).

Frequencies are defined in accordance with current guidance, as: Very common (≥1/10); common (≥1/100, <1/10); uncommon (≥1/1 000, <1/100); rare (≥1/10 000, <1/1 000); very rare (<1/10 000); not known (cannot be estimated from the available data).

Body System	**Incidence**	**Reported Adverse Event (Preferred Term)**
Immune System Disorders	Common Not known	Hypersensitivity[a] Anaphylactic reaction[a]
Psychiatric disorders	Uncommon	Abnormal dreams[*]
Nervous System Disorders	Very common Common Common Common Common Not known	Headache[a#] Burning sensation[c] Dizziness Dysgeusia Paraesthesia[a] Seizures
Eye Disorders	Not known Not known	Blurred Vision Lacrimation increased
Cardiac Disorders	Uncommon Uncommon Not known	Palpitations[a] Tachycardia[a] Atrial fibrillation
Vascular Disorders	Uncommon Uncommon	Flushing[a] Hypertension[a]

Respiratory, Thoracic and Mediastinal Disorders	Common	Cough**
	Very common	Hiccups****
	Very common	Throat irritation**
	Uncommon	Bronchospasm
	Uncommon	Dysphonia
	Uncommon	Dyspnoea[a]
	Uncommon	Nasal congestion
	Uncommon	Oropharyngeal pain
	Uncommon	Rhinorrhoea
	Uncommon	Sneezing
	Uncommon	Throat tightness
Gastrointestinal Disorders	Very common	Nausea[a]
	Common	Abdominal pain
	Common	Diarrhoea***
	Common	Dry mouth
	Common	Dyspepsia
	Common	Flatulence
	Common	Salivary hypersecretion
	Common	Stomatitis
	Common	Toothache
	Common	Vomiting[a]
	Uncommon	Eructation
	Uncommon	Gingivitis
	Uncommon	Glossitis
	Uncommon	Oral mucosal blistering and exfoliation
	Uncommon	Paraesthesia oral***
	Rare	Dysphagia
	Rare	Hypoaesthesia oral***
	Rare	Retching
	Not known	Dry throat
	Not known	Gastrointestinal discomfort[a]
	Not known	Lip pain
Musculoskeletal and connective tissue disorders	Uncommon	Pain in jaw[b]
	Uncommon	Musculoskeletal pain
	Not known	Muscle tightness[b]
Skin and Subcutaneous Tissue Disorders	Uncommon	Dry skin
	Uncommon	Hyperhidrosis[a]
	Uncommon	Pruritus[a]
	Uncommon	Rash[a]
	Uncommon	Urticaria**
	Not known	Angioedema[a]
	Not known	Erythema[a]
General disorders and administration site conditions:	Common	Fatigue[a]
	Uncommon	Asthenia[a]
	Uncommon	Chest discomfort and pain[a]
	Uncommon	Malaise

[a] Systemic effects; [b] Tightness of jaw and pain in jaw with nicotine gum formulation

[c] At the application site

*Identified only for formulations applied during the night

**Higher frequency observed in clinical studies with inhaler formulation.
***Reported the same or less frequently than placebo
**** Higher frequency observed in clinical studies with mouth spray formulation
# Although the frequency in the active group is less than that of the placebo group, the frequency in the specific formulation in which the PT was identified as a systemic ADR was greater in the active group than the placebo group.

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store

4.9 Overdose

When used as directed, symptoms of overdose with nicotine may occur in patients with low pre-treatment nicotine intake or if other sources of nicotine are used concomitantly.

Symptoms: Symptoms of overdose with nicotine from this product may occur in smokers/vapers who have previously had a low nicotine intake from cigarettes/e-cigarettes or if other sources of nicotine are used concomitantly with this product.
Acute or chronic toxicity of nicotine in man is highly dependent on mode and route of administration. Adaptation to nicotine (e.g. in smokers/vapers) is known to significantly increase tolerability compared with non-smokers/vapers.
The minimum lethal dose of nicotine in a non-tolerant man has been estimated to be 40 to 60mg. Symptoms of overdose are those of acute nicotine poisoning and include nausea, vomiting, increased salivation, abdominal pain, diarrhoea, sweating, headache, dizziness, disturbed hearing and marked weakness. At high doses, these symptoms may be followed by hypotension, rapid or weak or irregular pulse, breathing difficulties, prostration, circulatory collapse and general convulsions.

Doses of nicotine that are tolerated by adult smokers/vapers during treatment may produce severe symptoms of poisoning in children and may prove fatal. Suspected nicotine poisoning in a child should be considered a medical emergency and treated immediately.

Management of an overdose: All nicotine intake should stop immediately and the patient should be treated symptomatically. Artificial respiration should be instituted if necessary. Activated charcoal reduces the gastro-intestinal absorption of nicotine.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Drug used in nicotine dependence.
ATC code: N07B A01

Nicotine is an agonist at nicotine receptors in the peripheral and central nervous system and has pronounced CNS and cardiovascular effects. Clinical studies have shown that nicotine replacement products can help smokers abstain from use by relieving these withdrawal symptoms.

A parallel, double-blind, placebo-controlled, randomised pharmacodynamic study conducted in solus, regular vapers has shown that the mouth spray is effective in relieving momentary urges to vape (cravings) following ad lib use of the spray over 11 hours. A significantly higher proportion of subjects ($p<0.001$) in the mouth spray group (82.6%) had a maximum reduction of at least 50% vs. baseline in momentary urges-to-vape scores during the two hours follow-up compared to the placebo group (55.1%).

Compared to nicotine gum or nicotine lozenge, the absorption of nicotine from the mouth spray is more rapid (section 5.2) and based on prior experience with nicotine replacement therapy, this will result in a faster onset of relief of cravings and other symptoms.

Increased appetite is a recognised symptom of nicotine withdrawal and post-cessation weight gain is common. Clinical trials have demonstrated that Nicotine Replacement Therapy can help control weight following a quit attempt.

5.2 Pharmacokinetic properties

The pharmacokinetics of nicotine has been extensively studied, and variations in delivery format have been found to have significant effects on rate and extent of absorption.

The pharmacokinetics of the mouth spray has been studied in 4 studies. The studies included 141 subjects.

Absorption

The oral spray form means that the nicotine dose is administered instantaneously, and as a result the absorption of nicotine from the mouth spray is rapid: In trials, nicotine uptake from the oral nicotine spray was detected at 2 minutes, the first timepoint tested.

A maximum concentration of 5.3 ng/mL is reached within 13 minutes after administration of a 2 mg dose. The nicotine AUCs over the first 10 minutes after administration of the mouth spray at a dose of 1 and 2 mg exceeds those of nicotine gum as well as nicotine lozenge at doses of 4 mg (0.48 and 0.64 h*ng/mL vs. 0.33 and 0.33 h*ng/mL).

AUC∞ estimates show the bioavailability of nicotine administered by mouth spray is somewhat higher than that of nicotine gum or lozenge. The AUC∞ of the mouth spray 2 mg measured 18.9 h*ng/mL as compared with 16.2 h*ng/mL for nicotine gum 2 mg. Allowing for differences in administered dose, bioavailability was also higher in a second study. The nicotine AUC∞ of the mouth spray 2 mg measured 14.0 h*ng/mL in comparison with 23.0 h*ng/mL and 26.7 h*ng/mL for and nicotine gum 4 mg and nicotine lozenge 4 mg, respectively.

Steady-state average nicotine plasma concentrations achieved after administration of the maximum dose (i.e. 2 sprays of the mouth spray 1 mg every 30 minutes) are approximately 28.8 ng/mL as compared with 23.3 ng/mL for nicotine gum 4 mg (1 gum, hourly) and 25.5 ng/mL for nicotine lozenge 4 mg (1 lozenge, hourly).

Given the rapid absorption and the similar, high relative bioavailability, the majority of the nicotine released from the mouth spray is apparently absorbed through the buccal mucosa.

Distribution

The volume of distribution following intravenous administration of nicotine is about 2 to 3 l/kg.

Plasma protein binding of nicotine is less than 5%. Therefore, changes in nicotine binding from use of concomitant drugs or alterations of plasma proteins by disease states would not be expected to have any significant effects on the nicotine pharmacokinetics.

Biotransformation

Nicotine metabolism and elimination are independent of the choice of nicotine formulation, and thus results from studies with intravenous administration of nicotine are used to describe biotransformation and elimination.

The major nicotine-eliminating organ is the liver, although the kidney and lung also metabolise nicotine. More than 20 metabolites of nicotine have been identified, all of which are believed to be less active than the parent compound.

The primary metabolite of nicotine in plasma, cotinine, has a half-life of 15 to 20 hours and concentrations that exceed nicotine by 10-fold.

Elimination

The average plasma clearance of nicotine is 70 l/hour and the half-life is 2-3 hours.

The primary urinary metabolites are cotinine (12% of the dose) and trans-3-hydroxy-cotinine (37% of the dose). About 10% of nicotine is excreted unchanged in the urine. As much as 30% of nicotine may be excreted unchanged in the urine with high flow rates and acidification of the urine below pH 5.

Linearity/non-linearity
There is only a small deviation from dose-linearity of AUC∞ and Cmax as shown when single doses of 1, 2, 3 and 4 sprays of the 1 mg mouth spray are given.

Characteristics in specific groups of subjects:

Renal Impairment
Progressive severity of renal impairment is associated with decreased total clearance of nicotine. Nicotine clearance was on average decreased by 50%, in subjects with severe renal impairment. Raised nicotine levels have been seen in smokers undergoing hemodialysis.

Hepatic Impairment
In smokers with liver cirrhosis but only mild liver impairment (Child-Pugh score 5) the pharmacokinetics of nicotine is unaffected. However, in smokers with moderately impaired liver (Child-Pugh score 7) total clearance has been reported to be reduced by 40-50%. There is no information available in subjects with a Child-Pugh score > 7.

Elderly
A minor reduction in total clearance of nicotine, not justifying adjustment of dosage, has been demonstrated in healthy elderly patients.

5.3 Preclinical safety data

Nicotine was positive in some *in vitro* genotoxicity tests but there are also negative results with the same test systems. Nicotine was negative in *in vivo* tests.

Animal experiments have shown that nicotine exposure results in decreased birth-weight, decreased litter size and decreased survival of offspring.
The results of carcinogenicity assays did not provide any clear evidence of a tumorigenic effect of nicotine.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Propylene glycol (E1520)
Anhydrous ethanol
Trometamol
Poloxamer 407 (containing butylated hydroxytoluene E321)
Glycerol (E422)
Sodium hydrogen carbonate
Levomenthol
Mint flavour
Cooling flavour
Sucralose
Acesulfame potassium

Hydrochloric acid
Purified water

6.2 Incompatibilities
Not applicable.

6.3 Shelf life
30 Months.

6.4 Special precautions for storage
Do not store above 30°C

6.5 Nature and contents of container
PET bottle containing 13.2 ml of solution. One bottle contains at least 150 sprays. The bottle is placed in a dispenser with a mechanical spray pump. Nicorette QuickMist SmartTrack 1mg/spray mouthspray: Includes an inactive NFC chip on the outer of the dispenser to allow smartphone connectivity.

Pack Sizes: 1, 2, 3, 4 and 6 dispensers

Not all pack sizes may be marketed.

6.6 Special precautions for disposal
Any unused product or waste material should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

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Station Hill
Reading
RG1 1LN
UK

8 MARKETING AUTHORISATION NUMBER(S)

PL 15513/0357

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

05/11/2024

10 DATE OF REVISION OF THE TEXT

11 March 2026

Summary of Product Characteristics

1 Name of the medicinal product

Nicorette QuickMist Cool Berry 1mg/spray mouthspray

Nicorette QuickMist Cool Berry SmartTrack 1mg/spray mouthspray

2 Qualitative and quantitative composition

0.07 ml contains 1 mg nicotine, corresponding to 1 mg nicotine/spray dose.

Excipients with known effect:
Ethanol (contains less than 100 mg of ethanol/spray dose).
Propylene glycol (E1520)
Butylated hydroxytoluene (E321)

For a full list of excipients see section 6.1.

3 Pharmaceutical form

Oromucosal spray.

A clear to weakly opalescent, colourless to light yellow solution

4 Clinical particulars

4.1 Therapeutic indications

This product relieves and/or prevents craving and nicotine withdrawal symptoms in nicotine dependence, such as those arising from the use of tobacco or electronic cigarettes. It is indicated to aid quitting or reduction prior to quitting, to assist those who are unwilling or unable to use such products, and as a safer alternative to smoking tobacco for smokers and those around them.

This product is indicated in pregnant and lactating women making a quit attempt.

4.2 Posology and method of administration

The patient should make every effort to stop smoking or vaping completely during treatment with this product.

Behavioural therapy, advice and support will normally improve the success rate.

Directions for use

For those using this product for the first time or those who have not used the spray for 2 days, they must first prime the spray pump.

Priming

1. Point the spray safely away from you and any other adults, children or pets that are near you.
2. Press the top of the QuickMist with your index finger 3 times until a fine spray appears.

Note: priming reduces the number of sprays you may get from this product.

After priming, point the spray nozzle as close to the open mouth as possible. Press the top of the dispenser and release one spray into your mouth, avoiding the lips. Do not inhale while spraying to avoid getting spray down your throat. For best results, do not swallow for a few seconds after spraying.
The patient should not eat or drink when administering the oromucosal spray.

Care should be taken not to spray the eyes whilst administering the mouth spray.

Adults and Children over 12 years of age

Use 1 or 2 sprays when you would normally have smoked or vaped or if cravings emerge. If after the first spray cravings are not controlled within a few minutes, a second spray should be used. If 2 sprays are required, future doses may be delivered as 2 consecutive sprays.

Most smokers will require 1-2 sprays every 30 minutes to 1 hour.

You may use up to 4 sprays per hour. Do not exceed 2 sprays per dosing episode and 64 sprays (4 sprays per hour over 16 hours) in any 24-hour period.

Each mouthspray contains at least 150 sprays.

This product should be used whenever the urge to smoke or vape is felt or to prevent cravings in situations where these are likely to occur.

Patients willing or able to stop smoking/vaping immediately should initially replace all their cigarettes/e-cigarettes with this product and as soon as they are able, reduce the number of sprays used until they have stopped completely.

Patients aiming to reduce cigarettes/e-cigarettes should use the Mouthspray, between smoking/vaping episodes, as needed, to prolong smoke/vape-free intervals and to reduce their use as much as possible.

As soon as they are ready patients should aim to quit smoking/vaping completely.

When making a quit attempt behavioural therapy, advice and support will normally improve the success rate. Those who have quit smoking/vaping but are having difficulty discontinuing their Mouthspray are recommended to contact their pharmacist or doctor for advice.

4.3 Contra-indications

Hypersensitivity to the active substance or to any of the excipients of the mouthspray listed in section 6.1.

This product is contraindicated in children under 12 years.

4.4 Special warnings and precautions for use

Any risks that may be associated with NRT are substantially outweighed by the well-established dangers of continued smoking. The risks of continued vaping are not yet established.

A risk-benefit assessment should be made by an appropriate healthcare professional for patients with the following conditions:

Underlying cardiovascular disease: In stable cardiovascular disease this product presents a lesser hazard than continuing to smoke. However dependent smokers currently hospitalised as a result of myocardial infarction, unstable or worsening angina including Prinzmetal's angina, severe dysrhythmia or cerebrovascular accident and who are considered to be haemodynamically unstable and/or who have uncontrolled hypertension should be encouraged to stop smoking with non-pharmacological interventions. If this fails, this product may be considered, but as data on safety in this patient group are limited, initiation should only be under medical supervision. The risks of continued vaping are not yet established.

Diabetes mellitus: Patients with diabetes mellitus should be advised to monitor their blood sugar levels more closely than usual when quitting, and NRT is initiated as reductions in nicotine induced catecholamines released by nicotine can affect carbohydrate metabolism.

GI disease: Nicotine may exacerbate symptoms in patients suffering from oesophagitis, gastritis or peptic ulcers and NRT preparations should be used with caution in these conditions.

Seizures: Potential risks and benefits of nicotine should be carefully evaluated before use in subjects with a history of epilepsy as cases of convulsions have been reported in association with nicotine.

Renal or hepatic impairment: This product should be used with caution in patients with moderate to severe hepatic impairment and/or severe renal impairment as the clearance of nicotine or its metabolites may be decreased with the potential for increased adverse effects.

Danger in children: Doses of nicotine tolerated by adult and adolescent smokers or vapers can produce severe toxicity in children that may be fatal. Products containing nicotine should not be left where they may be misused, handled or ingested by children. See Section 4.9 Overdose.

Phaeochromocytoma and uncontrolled hyperthyroidism: As nicotine causes release of catecholamines, this product should be used with caution in patients with uncontrolled hyperthyroidism or phaeochromocytoma.

Transferred dependence: Transferred dependence is rare and is both less harmful and easier to break than smoking dependence.

Stopping smoking: Polycyclic aromatic hydrocarbons in tobacco smoke induce the metabolism of drugs metabolised by CYP 1A2 (and possibly by CYP 1A1). When a smoker stops smoking, this may result in slower metabolism and a consequent rise in blood levels of such drugs. This is of potential clinical importance for products with a narrow therapeutic window, e.g. theophylline, clozapine and ropinirole.

Excipients: The mouthspray contains about 7 mg of alcohol (ethanol) in each spray which is equivalent to 97 mg/ml. The amount in one spray of this medicine is equivalent to less than 2 ml beer or 1 ml wine. The small amount of alcohol in this medicine will not have any noticeable effects. This medicine contains 12 mg propylene glycol in each spray which is equivalent to 157 mg/mL. Due to the presence of a small amount of butylated hydroxytoluene (BHT), this medicine may cause local skin reactions (e.g. contact dermatitis), or irritation to the eyes and mucous membranes. This medicine contains less than 1 mmol sodium (23 mg) per spray, i.e. is essentially 'sodium- free'.

Care should be taken not to spray the eyes whilst administering the spray.

4.5 Interaction with other medicinal products and other forms of interactions

No clinically relevant interactions between nicotine replacement therapy and other drugs have definitely been established. However nicotine may possibly enhance the haemodynamic effects of adenosine i.e. increase in blood pressure and heart rate and also increase pain response (angina-pectoris type chest pain) provoked by adenosine administration.

4.6 Fertility, pregnancy and lactation

Fertility

In females tobacco smoking delays time to conception, decreases in-vitro fertilization success rates, and significantly increases the risk of infertility.

In males tobacco smoking reduces sperm production, increases oxidative stress, and DNA damage. Spermatozoa from smokers have reduced fertilizing capacity.

The specific contribution of nicotine to these effects in humans is unknown.

There is no or limited data regarding the effect of vaping on fertility.

Pregnancy

Stopping smoking is the single most effective intervention for improving the health of both the pregnant smoker and her baby, and the earlier abstinence is achieved the better. Ideally smoking cessation during pregnancy should be achieved without NRT. Nicotine passes to the foetus and affects its breathing movements and circulation. The effect on the circulation is dose-dependent. However, if the mother cannot (or is considered unlikely to) quit without pharmacological support, NRT may be used as the risk to the fetus is lower than that expected with smoking tobacco. Stopping completely is by far the best option but if this is not achievable this product may be used in pregnancy as a safer alternative to smoking. Because of the potential for nicotine-free periods, intermittent dose forms are preferable, but patches may be considered as an alternative if there is significant nausea and/or vomiting. If patches are used they should, if possible, be removed at night when the fetus would not normally be exposed to nicotine.

Use of nicotine by the pregnant smoker should only be initiated after advice from a health care professional.

There is no or limited data regarding the effect of vaping in pregnancy.

Lactation

Nicotine should be avoided during breast-feeding. The relatively small amounts of nicotine found in breast milk during NRT use are less hazardous to the infant than second-hand smoke. Intermittent dose forms would minimize the amount of nicotine in breast milk and permit feeding when levels were at their lowest.

Use of the nicotine by breast feeding smokers should only be initiated after advice from a health care professional. Women should take the product as soon as possible after breastfeeding.

There is no or limited data regarding the effect of vaping in lactating women.

4.7 Effects on ability to drive and use machines

This product has no or negligible influence on the ability to drive and use machines.

4.8 Undesirable effects

Effects of smoking Cessation

Some symptoms may be related to nicotine withdrawal associated with stopping smoking. These can include the following: dysphoria or depressed mood; insomnia; irritability, frustration or anger; anxiety; difficulty concentrating, restlessness or impatience; decreased heart rate; and increased appetite or weight gain. These have been observed in those using the mouthspray.

Increased frequency of aphthous ulcer, cough and nasopharyngitis may occur after abstinence from smoking. The causality is unclear.

In addition to this, other cessation-associated symptoms were seen in those using the mouth spray: dizziness, presyncopal symptoms, constipation, and gingival bleeding.

Nicotine craving, which is recognised as a clinically relevant symptom, is an important element in nicotine withdrawal after smoking cessation.

Effects of vaping Cessation

The nicotine withdrawal effects of vaping cessation have not been established, however it is anticipated that many of the effects relating to nicotine withdrawal will be the same as those seen with tobacco smoking cessation.

Adverse Drug Reactions

This product may cause adverse reactions similar to those associated with nicotine given by other means, including smoking and vaping, and these are mainly dose-dependent.

Most adverse events reported with this product occur during the early phase of treatment and are similar to those seen with other orally delivered forms. During the first few days of treatment irritation to the mouth and throat may be experienced and hiccups are particularly common. Tolerance is normal with continued use.

Daily collection of data from trial subjects demonstrated that very commonly occurring adverse events were reported with onset in the first 2-3 weeks of use of the spray, and declined thereafter.

Allergic reactions (including symptoms of anaphylaxis) occur rarely during use of this product.

The adverse reactions observed in patients treated with oral nicotine formulations during clinical trials and post-marketing experience are listed below by System Organ Class (SOC).

Frequencies are defined in accordance with current guidance, as: Very common (≥1/10); common (≥1/100, <1/10); uncommon (≥1/1 000, <1/100); rare (≥1/10 000, <1/1 000); very rare (<1/10 000); not known (cannot be estimated from the available data).

Body System	Incidence	Reported Adverse Event (Preferred Term)
Immune System Disorders	Common Not known	Hypersensitivity[a] Anaphylactic reaction[a]
Psychiatric disorders	Uncommon	Abnormal dreams[*]
Nervous System Disorders	Very common Common Common Common Common Not known	Headache[a#] Burning sensation[c] Dizziness Dysgeusia Paraesthesia[a] Seizures
Eye Disorders	Not known Not known	Blurred Vision Lacrimation increased
Cardiac Disorders	Uncommon Uncommon Not known	Palpitations[a] Tachycardia[a] Atrial fibrillation
Vascular Disorders	Uncommon Uncommon	Flushing[a] Hypertension[a]
Respiratory, Thoracic and Mediastinal Disorders	Common Very common Very common Uncommon Uncommon Uncommon Uncommon Uncommon Uncommon Uncommon	Cough** Hiccups**** Throat irritation ** Bronchospasm Dysphonia Dyspnoea[a] Nasal congestion Oropharyngeal pain Rhinorrhoea Sneezing Throat tightness
Gastrointestinal Disorders	Very common Common Common Common Common Common Common Common Common Uncommon Uncommon Uncommon Uncommon Uncommon Rare Rare Rare Not known Not known Not known	Nausea[a] Abdominal pain Diarrhoea*** Dry mouth Dyspepsia Flatulence Salivary hypersecretion Stomatitis Toothache Vomiting[a] Eructation Gingivitis Glossitis Oral mucosal blistering and exfoliation Paraesthesia oral*** Dysphagia Hypoaesthesia oral*** Retching Dry throat Gastrointestinal discomfort[a] Lip pain
Musculoskeletal and connective tissue disorders	Uncommon Uncommon Not known	Pain in jaw[b] Musculoskeletal pain Muscle tightness[b]
Skin and Subcutaneous Tissue Disorders	Uncommon Uncommon Uncommon Uncommon	Dry skin Hyperhidrosis[a] Pruritus[a] Rash[a]

	Uncommon Not known Not known	Urticaria** Angioedema[a] Erythema[a]
General disorders and administration site conditions:	Common Uncommon Uncommon Uncommon	Fatigue[a] Asthenia[a] Chest discomfort and pain[a] Malaise

[a] Systemic effects; [b] Tightness of jaw and pain in jaw with nicotine gum formulation
[c] At the application site
*Identified only for formulations applied during the night
**Higher frequency observed in clinical studies with inhaler formulation.
***Reported the same or less frequently than placebo
**** Higher frequency observed in clinical studies with mouth spray formulation
[#] Although the frequency in the active group is less than that of the placebo group, the frequency in the specific formulation in which the PT was identified as a systemic ADR was greater in the active group than the placebo group.

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store

4.9 Overdose

When used as directed, symptoms of overdose with nicotine may occur in patients with low pre-treatment nicotine intake or if other sources of nicotine are used concomitantly.

Symptoms: Symptoms of overdose with nicotine from this product may occur in smokers/vapers who have previously had a low nicotine intake from cigarettes/ e-cigarettes or if other sources of nicotine are used concomitantly with this product. Acute or chronic toxicity of nicotine in man is highly dependent on mode and route of administration. Adaptation to nicotine (e.g. in smokers/vapers) is known to significantly increase tolerability compared with non-smokers/vapers.
The minimum lethal dose of nicotine in a non-tolerant man has been estimated to be 40 to 60mg. Symptoms of overdose are those of acute nicotine poisoning and include nausea, vomiting, increased salivation, abdominal pain, diarrhoea, sweating, headache, dizziness, disturbed hearing and marked weakness. At high doses, these symptoms may be followed by hypotension, rapid or weak or irregular pulse, breathing difficulties, prostration, circulatory collapse and general convulsions.

Doses of nicotine that are tolerated by adult smokers/vapers during treatment may produce severe symptoms of poisoning in children and may prove fatal. Suspected nicotine poisoning in a child should be considered a medical emergency and treated immediately.

Management of an overdose: All nicotine intake should stop immediately and the patient should be treated symptomatically. Artificial respiration should be instituted if necessary. Activated charcoal reduces the gastro-intestinal absorption of nicotine.

5 Pharmacological properties

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Drug used in nicotine dependence.

ATC code: N07B A01

Nicotine is an agonist at nicotine receptors in the peripheral and central nervous system and has pronounced CNS and cardiovascular effects.

Clinical studies have shown that nicotine replacement products can help smokers abstain from use by relieving these withdrawal symptoms.

A parallel, double-blind, placebo-controlled, randomised pharmacodynamic study conducted in solus, regular vapers has shown that the mouth spray is effective in relieving momentary urges to vape (cravings) following ad lib use of the spray over 11 hours. A significantly higher proportion of subjects ($p<0.001$) in the mouth spray group (82.6%) had a maximum reduction of at least 50% vs. baseline in momentary urges-to-vape scores during the two hours follow-up compared to the placebo group (55.1%).

Compared to nicotine gum or nicotine lozenge, the absorption of nicotine from the mouth spray is more rapid (section 5.2) and based on prior experience with nicotine replacement therapy, this will result in a faster onset of relief of cravings and other symptoms.

Increased appetite is a recognised symptom of nicotine withdrawal and post-cessation weight gain is common. Clinical trials have demonstrated that Nicotine Replacement Therapy can help control weight following a quit attempt.

5.2 Pharmacokinetic properties

The pharmacokinetics of nicotine has been extensively studied, and variations in delivery format have been found to have significant effects on rate and extent of absorption.

The pharmacokinetics of the mouth spray has been studied in 4 studies. The studies included 141 subjects.

Absorption

The oral spray form means that the nicotine dose is administered instantaneously, and as a result the absorption of nicotine from the mouth spray is rapid: In trials, nicotine uptake from the oral nicotine spray was detected at 2 minutes, the first timepoint tested.

A maximum concentration of 5.3 ng/mL is reached within 13 minutes after administration of a 2 mg dose. The nicotine AUCs over the first 10 minutes after administration of the mouth spray at a dose of 1 and 2 mg exceeds those of nicotine gum as well as nicotine lozenge at doses of 4 mg (0.48 and 0.64 h*ng/mL vs. 0.33 and 0.33 h*ng/mL).

AUC∞ estimates show the bioavailability of nicotine administered by mouth spray is somewhat higher than that of nicotine gum or lozenge. The AUC∞ of the mouth spray 2 mg measured 18.9 h*ng/mL as compared with 16.2 h*ng/mL for nicotine gum 2 mg. Allowing for differences in administered dose, bioavailability was also higher in a second study. The nicotine AUC∞ of the mouth spray 2 mg measured 14.0 h*ng/mL in comparison with 23.0 h*ng/mL and 26.7 h*ng/mL for and nicotine gum 4 mg and nicotine lozenge 4 mg, respectively.

Steady-state average nicotine plasma concentrations achieved after administration of the maximum dose (i.e. 2 sprays of the mouth spray 1 mg every 30 minutes) are approximately 28.8 ng/mL as compared with 23.3 ng/mL for nicotine gum 4 mg (1 gum, hourly) and 25.5 ng/mL for nicotine lozenge 4 mg (1 lozenge, hourly).

Given the rapid absorption and the similar, high relative bioavailability, the majority of the nicotine released from the mouth spray is apparently absorbed through the buccal mucosa.

Distribution

The volume of distribution following intravenous administration of nicotine is about 2 to 3 l/kg.

Plasma protein binding of nicotine is less than 5%. Therefore, changes in nicotine binding from use of concomitant drugs or alterations of plasma proteins by disease states would not be expected to have any significant effects on the nicotine pharmacokinetics.

Biotransformation

Nicotine metabolism and elimination are independent of the choice of nicotine formulation, and thus results from studies with intravenous administration of nicotine are used to describe biotransformation and elimination.

The major nicotine-eliminating organ is the liver, although the kidney and lung also metabolise nicotine. More than 20 metabolites of nicotine have been identified, all of which are believed to be less active than the parent compound.

The primary metabolite of nicotine in plasma, cotinine, has a half-life of 15 to 20 hours and concentrations that exceed nicotine by 10-fold.

Elimination

The average plasma clearance of nicotine is 70 l/hour and the half-life is 2-3 hours.

The primary urinary metabolites are cotinine (12% of the dose) and trans-3-hydroxy-cotinine (37% of the dose). About 10% of nicotine is excreted unchanged in the urine. As much as 30% of nicotine may be excreted unchanged in the urine with high flow rates and acidification of the urine below pH 5.

Linearity/non-linearity

There is only a small deviation from dose-linearity of AUC∞ and Cmax as shown when single doses of 1, 2, 3 and 4 sprays of the 1 mg mouth spray are given.

Characteristics in specific groups of subjects:

Renal Impairment

Progressive severity of renal impairment is associated with decreased total clearance of nicotine. Nicotine clearance was on average decreased by 50%, in subjects with severe renal impairment. Raised nicotine levels have been seen in smokers undergoing hemodialysis.

Hepatic Impairment

In smokers with liver cirrhosis but only mild liver impairment (Child-Pugh score 5) the pharmacokinetics of nicotine is unaffected. However, in smokers with moderately impaired liver (Child-Pugh score 7) total clearance has been reported to be reduced by 40-50%. There is no information available in subjects with a Child-Pugh score > 7.

Elderly

A minor reduction in total clearance of nicotine, not justifying adjustment of dosage, has been demonstrated in healthy elderly patients.

5.3 Preclinical safety data

Nicotine was positive in some *in vitro* genotoxicity tests but there are also negative results with the same test systems. Nicotine was negative in *in vivo* tests.

Animal experiments have shown that nicotine exposure results in decreased birth-weight, decreased litter size and decreased survival of offspring.

The results of carcinogenicity assays did not provide any clear evidence of a tumorigenic effect of nicotine.

6 Pharmaceutical particulars

6.1 List of Excipients

Propylene glycol (E1520)
Anhydrous ethanol
Trometamol
Poloxamer 407 (containing butylated hydroxytoluene E321)
Glycerol (E422)
Sodium hydrogen carbonate
Levomenthol
Red fruits flavour
Cooling flavour
Sucralose

Acesulfame potassium
Hydrochloric acid
Purified water

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

2 years

6.4 Special precautions for storage

Do not store above 25°C

6.5 Nature and contents of container

PET bottle containing 13.2 ml of solution. One bottle contains at least 150 sprays. The bottle is placed in a dispenser with a mechanical spray pump.

Nicorette QuickMist Cool Berry SmartTrack 1mg/spray mouthspray: Includes an inactive NFC chip on the outer of the dispenser to allow smartphone connectivity.

Pack Sizes: 1 dispenser, 2 dispensers

Not all pack sizes may be marketed.

6.6 Special precautions for disposal

Any unused product or waste material should be disposed of in accordance with local requirements.

7 Marketing authorisation holder

McNeil Products Limited
1 Station Hill Square
Station Hill
Reading
RG1 1LN
UK

8 Marketing authorisation number

PL 15513/0395

9 Date of the first authorisation or renewal

13th June 2018

10 Date of revision of the text

06 Mar 2026

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Nicorette QuickMist Spearmint 1mg/spray mouthspray

Nicorette QuickMist Spearmint SmartTrack 1mg/spray mouthspray

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

0.07 ml contains 1 mg nicotine, corresponding to 1 mg nicotine/spr-ay dose.

Excipients with known effect:
Ethanol 7.1mg/spray
Propylene glycol 11.7mg/spray
Butylated hydroxytoluene 368ng/spray

For a full list of excipients see section 6.1.

3 PHARMACEUTICAL FORM

Oromucosal spray.

A clear to weakly opalescent, colourless to light yellow solution

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

This product relieves and/or prevents craving and nicotine withdrawal symptoms in nicotine dependence, such as those arising from the use of tobacco or electronic cigarettes. It is indicated to aid quitting or reduction prior to quitting, to assist those who are unwilling or unable to use such products, and as a safer alternative to smoking tobacco for smokers and those around them.

This product is indicated in pregnant and lactating women making a quit attempt.

4.2 Posology and method of administration

The patient should make every effort to stop smoking or vaping completely during treatment with this product.

Behavioural therapy, advice and support will normally improve the success rate.

Directions for use

For those using this product for the first time or those who have not used the spray for 2 days, they must first prime the spray pump.

Priming

1. Point the spray safely away from you and any other adults, children or pets that are near you.
2. Press the top of the QuickMist with your index finger 3 times until a fine spray appears.

Note: priming reduces the number of sprays you may get from this product.

After priming, point the spray nozzle as close to the open mouth as possible. Press the top of the dispenser and release one spray into your mouth, avoiding the lips. Do not inhale while spraying to avoid getting spray down your throat. For best results, do not swallow for a few seconds after spraying.
The patient should not eat or drink when administering the oromucosal spray.

Care should be taken not to spray the eyes whilst administering the mouth spray.

Adults and Children over 12 years of age

Use 1 or 2 sprays when you would normally have smoked or vaped or if cravings emerge. If after the first spray cravings are not controlled within a few minutes, a second spray should be used. If 2 sprays are required, future doses may be delivered as 2 consecutive sprays.

Most smokers will require 1-2 sprays every 30 minutes to 1 hour.

You may use up to 4 sprays per hour. Do not exceed 2 sprays per dosing episode and 64 sprays (4 sprays per hour over 16 hours) in any 24-hour period.

Each mouthspray contains at least 150 sprays.

This product should be used whenever the urge to smoke or vape is felt or to prevent cravings in situations where these are likely to occur.

Patients willing or able to stop smoking/vaping immediately should initially replace all their cigarettes/e-cigarettes with this product and as soon as they are able, reduce the number of sprays used until they have stopped completely.

Patients aiming to reduce cigarettes/e-cigarettes should use the Mouthspray, between smoking/vaping episodes, as needed, to prolong smoke/vape-free intervals and to reduce their use as much as possible.

As soon as they are ready patients should aim to quit smoking/vaping completely.

When making a quit attempt behavioural therapy, advice and support will normally improve the success rate. Those who have quit smoking/vaping but are having difficulty discontinuing their Mouthspray are recommended to contact their pharmacist or doctor for advice.

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4.4 Special warnings and precautions for use

Any risks that may be associated with NRT are substantially outweighed by the well-established dangers of continued smoking. The risks of continued vaping are not yet established.

A risk-benefit assessment should be made by an appropriate healthcare professional for patients with the following conditions:

Underlying cardiovascular disease: In stable cardiovascular disease this product presents a lesser hazard than continuing to smoke. However dependent smokers currently hospitalised as a result of myocardial infarction, unstable or worsening angina including Prinzmetal's angina, severe dysrhythmia or cerebrovascular accident and who are considered to be haemodynamically unstable and/or who have uncontrolled hypertension should be encouraged to stop smoking with non-pharmacological interventions. If this fails, this product may be considered, but as data on safety in this patient group are limited, initiation should only be under medical supervision. The risks of continued vaping are not yet established.

Diabetes mellitus: Patients with diabetes mellitus should be advised to monitor their blood sugar levels more closely than usual when quitting, and NRT is initiated as reductions in nicotine induced catecholamines released by nicotine can affect carbohydrate metabolism.

GI disease: Nicotine may exacerbate symptoms in patients suffering from oesophagitis, gastritis or peptic ulcers and NRT preparations should be used with caution in these conditions.

Seizures: Potential risks and benefits of nicotine should be carefully evaluated before use in subjects with a history of epilepsy as cases of convulsions have been reported in association with nicotine.

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Danger in children: Doses of nicotine tolerated by adult and adolescent smokers or vapers can produce severe toxicity in children that may be fatal. Products containing nicotine should not be left where they may be misused, handled or ingested by children. See Section 4.9 Overdose.

Phaeochromocytoma and uncontrolled hyperthyroidism: As nicotine causes release of catecholamines, this product should be used with caution in patients with uncontrolled hyperthyroidism or phaeochromocytoma.

Transferred dependence: Transferred dependence is rare and is both less harmful and easier to break than smoking dependence.

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In females tobacco smoking delays time to conception, decreases in-vitro fertilization success rates, and significantly increases the risk of infertility.

In males tobacco smoking reduces sperm production, increases oxidative stress, and DNA damage. Spermatozoa from smokers have reduced fertilizing capacity.

The specific contribution of nicotine to these effects in humans is unknown.

There is no or limited data regarding the effect of vaping on fertility.

Pregnancy

Stopping smoking is the single most effective intervention for improving the health of both the pregnant smoker and her baby, and the earlier abstinence is achieved the better. Ideally smoking cessation during pregnancy should be achieved without NRT. Nicotine passes to the foetus and affects its breathing movements and circulation. The effect on the circulation is dose-dependent. However, if the mother cannot (or is considered unlikely to) quit without pharmacological support, NRT may be used as the risk to the fetus is lower than that expected with smoking tobacco. Stopping completely is by far the best option but if this is not achievable this product may be used in pregnancy as a safer alternative to smoking. Because of the potential for nicotine-free periods, intermittent dose forms are preferable, but patches may be considered as an alternative if there is significant nausea and/or vomiting. If patches are used they should, if possible, be removed at night when the fetus would not normally be exposed to nicotine.

Use of nicotine by the pregnant smoker should only be initiated after advice from a health care professional.

There is no or limited data regarding the effect of vaping in pregnancy.

Lactation

Nicotine should be avoided during breast-feeding. The relatively small amounts of nicotine found in breast milk during NRT use are less hazardous to the infant than second-hand smoke. Intermittent dose forms would minimize the amount of nicotine in breast milk and permit feeding when levels were at their lowest.

Use of the nicotine by breast feeding smokers should only be initiated after advice from a health care professional. Women should take the product as soon as possible after breastfeeding.

There is no or limited data regarding the effect of vaping in lactating women.

4.7 Effects on ability to drive and use machines

This product has no or negligible influence on the ability to drive and use machines.

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Some symptoms may be related to nicotine withdrawal associated with stopping smoking. These can include the following: dysphoria or depressed mood; insomnia; irritability, frustration or anger; anxiety; difficulty concentrating, restlessness or impatience; decreased heart rate; and increased appetite or weight gain. These have been observed in those using the mouthspray.

Increased frequency of aphthous ulcer, cough and nasopharyngitis may occur after abstinence from smoking. The causality is unclear.

In addition to this, other cessation-associated symptoms were seen in those using the mouth spray: dizziness, presyncopal symptoms, constipation, and gingival bleeding.

Nicotine craving, which is recognised as a clinically relevant symptom, is an important element in nicotine withdrawal after smoking cessation.

Effects of vaping Cessation

The nicotine withdrawal effects of vaping cessation have not been established, however it is anticipated that many of the effects relating to nicotine withdrawal will be the same as those seen with tobacco smoking cessation.

Adverse Drug Reactions

This product may cause adverse reactions similar to those associated with nicotine given by other means, including smoking and vaping, and these are mainly dose-dependent.

Most adverse events reported with this product occur during the early phase of treatment and are similar to those seen with other orally delivered forms. During the first few days of treatment irritation to the mouth and throat may be experienced and hiccups are particularly common. Tolerance is normal with continued use.

Daily collection of data from trial subjects demonstrated that very commonly occurring adverse events were reported with onset in the first 2-3 weeks of use of the spray, and declined thereafter.

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The adverse reactions observed in patients treated with oral nicotine formulations during clinical trials and post-marketing experience are listed below by System Organ Class (SOC).

Frequencies are defined in accordance with current guidance, as: Very common (≥1/10); common (≥1/100, <1/10); uncommon (≥1/1 000, <1/100); rare (≥1/10 000, <1/1 000); very rare (<1/10 000); not known (cannot be estimated from the available data).

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Psychiatric disorders	Uncommon	Abnormal dreams[*]
Nervous System Disorders	Very common Common Common Common Common Not known	Headache[a#] Burning sensation[c] Dizziness Dysgeusia Paraesthesia[a] Seizures
Eye Disorders	Not known Not known	Blurred Vision Lacrimation increased
Cardiac Disorders	Uncommon Uncommon Not known	Palpitations[a] Tachycardia[a] Atrial fibrillation
Vascular Disorders	Uncommon Uncommon	Flushing[a] Hypertension[a]
Respiratory, Thoracic and Mediastinal Disorders	Common Very common Very common Uncommon Uncommon Uncommon Uncommon Uncommon Uncommon Uncommon	Cough** Hiccups**** Throat irritation ** Bronchospasm Dysphonia Dyspnoea[a] Nasal congestion Oropharyngeal pain Rhinorrhoea Sneezing Throat tightness
Gastrointestinal Disorders	Very common Common Common Common Common Common Common Common Common Uncommon Uncommon Uncommon Uncommon Uncommon Rare Rare Rare Not known Not known Not known	Nausea[a] Abdominal pain Diarrhoea*** Dry mouth Dyspepsia Flatulence Salivary hypersecretion Stomatitis Toothache Vomiting[a] Eructation Gingivitis Glossitis Oral mucosal blistering and exfoliation Paraesthesia oral*** Dysphagia Hypoaesthesia oral*** Retching Dry throat Gastrointestinal discomfort[a] Lip pain
Musculoskeletal and connective tissue disorders	Uncommon Uncommon Not known	Pain in jaw[b] Musculoskeletal pain Muscle tightness[b]

Skin and Subcutaneous Tissue Disorders	Uncommon Uncommon Uncommon Uncommon Uncommon Not known Not known	Dry skin Hyperhidrosis[a] Pruritus[a] Rash[a] Urticaria** Angioedema[a] Erythema[a]
General disorders and administration site conditions:	Common Uncommon Uncommon Uncommon	Fatigue[a] Asthenia[a] Chest discomfort and pain[a] Malaise

[a] Systemic effects; [b] Tightness of jaw and pain in jaw with nicotine gum formulation
[c] At the application site
*Identified only for formulations applied during the night
**Higher frequency observed in clinical studies with inhaler formulation.
***Reported the same or less frequently than placebo
**** Higher frequency observed in clinical studies with mouth spray formulation
[#] Although the frequency in the active group is less than that of the placebo group, the frequency in the specific formulation in which the PT was identified as a systemic ADR was greater in the active group than the placebo group.

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store

4.9 Overdose

When used as directed, symptoms of overdose with nicotine may occur in patients with low pre-treatment nicotine intake or if other sources of nicotine are used concomitantly.

Symptoms: Symptoms of overdose with nicotine from this product may occur in smokers/vapers who have previously had a low nicotine intake from cigarettes/ e-cigarettes or if other sources of nicotine are used concomitantly with this product. Acute or chronic toxicity of nicotine in man is highly dependent on mode and route of administration. Adaptation to nicotine (e.g. in smokers/vapers) is known to significantly increase tolerability compared with non-smokers/vapers.
The minimum lethal dose of nicotine in a non-tolerant man has been estimated to be 40 to 60mg. Symptoms of overdose are those of acute nicotine poisoning and include nausea, vomiting, increased salivation, abdominal pain, diarrhoea, sweating, headache, dizziness, disturbed hearing and marked weakness. At high doses, these symptoms may be followed by hypotension, rapid or weak or irregular pulse, breathing difficulties, prostration, circulatory collapse and general convulsions.

Doses of nicotine that are tolerated by adult smokers/vapers during treatment may produce severe symptoms of poisoning in children and may prove fatal. Suspected nicotine poisoning in a child should be considered a medical emergency and treated immediately.

Management of an overdose: All nicotine intake should stop immediately and the patient should be treated symptomatically. Artificial respiration should be instituted if necessary. Activated charcoal reduces the gastro-intestinal absorption of nicotine.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Drug used in nicotine dependence.

ATC code: N07B A01

Nicotine is an agonist at nicotine receptors in the peripheral and central nervous system and has pronounced CNS and cardiovascular effects.

Clinical studies have shown that nicotine replacement products can help smokers abstain from use by relieving these withdrawal symptoms.

A parallel, double-blind, placebo-controlled, randomised pharmacodynamic study conducted in solus, regular vapers has shown that the mouth spray is effective in relieving momentary urges to vape (cravings) following ad lib use of the spray over 11 hours. A significantly higher proportion of subjects ($p<0.001$) in the mouth spray group (82.6%) had a maximum reduction of at least 50% vs. baseline in momentary urges-to-vape scores during the two hours follow-up compared to the placebo group (55.1%).

Compared to nicotine gum or nicotine lozenge, the absorption of nicotine from the mouth spray is more rapid (section 5.2) and based on prior experience with nicotine replacement therapy, this will result in a faster onset of relief of cravings and other symptoms.

Increased appetite is a recognised symptom of nicotine withdrawal and post-cessation weight gain is common. Clinical trials have demonstrated that Nicotine Replacement Therapy can help control weight following a quit attempt.

5.2 Pharmacokinetic properties

The pharmacokinetics of nicotine has been extensively studied, and variations in delivery format have been found to have significant effects on rate and extent of absorption.

The pharmacokinetics of the mouth spray has been studied in 4 studies. The studies included 141 subjects.

Absorption

The oral spray form means that the nicotine dose is administered instantaneously, and as a result the absorption of nicotine from the mouth spray is rapid: In trials, nicotine uptake from the oral nicotine spray was detected at 2 minutes, the first timepoint tested.

A maximum concentration of 5.3 ng/mL is reached within 13 minutes after administration of a 2 mg dose. The nicotine AUCs over the first 10 minutes after administration of the mouth spray at a dose of 1 and 2 mg exceeds those of nicotine gum as well as nicotine lozenge at doses of 4 mg (0.48 and 0.64 h*ng/mL vs. 0.33 and 0.33 h*ng/mL).

AUC∞ estimates show the bioavailability of nicotine administered by mouth spray is somewhat higher than that of nicotine gum or lozenge. The AUC∞ of the mouth spray 2 mg measured 18.9 h*ng/mL as compared with 16.2 h*ng/mL for nicotine gum 2 mg. Allowing for differences in administered dose, bioavailability was also higher in a second study. The nicotine AUC∞ of the mouth spray 2 mg measured 14.0 h*ng/mL in comparison with 23.0 h*ng/mL and 26.7 h*ng/mL for and nicotine gum 4 mg and nicotine lozenge 4 mg, respectively.

Steady-state average nicotine plasma concentrations achieved after administration of the maximum dose (i.e. 2 sprays of the mouth spray 1 mg every 30 minutes) are approximately 28.8 ng/mL as compared with 23.3 ng/mL for nicotine gum 4 mg (1 gum, hourly) and 25.5 ng/mL for nicotine lozenge 4 mg (1 lozenge, hourly).

Given the rapid absorption and the similar, high relative bioavailability, the majority of the nicotine released from the mouth spray is apparently absorbed through the buccal mucosa.

Distribution

The volume of distribution following intravenous administration of nicotine is about 2 to 3 l/kg.

Plasma protein binding of nicotine is less than 5%. Therefore, changes in nicotine binding from use of concomitant drugs or alterations of plasma proteins by disease states would not be expected to have any significant effects on the nicotine pharmacokinetics.

Biotransformation

Nicotine metabolism and elimination are independent of the choice of nicotine formulation, and thus results from studies with intravenous administration of nicotine are used to describe biotransformation and elimination.

The major nicotine-eliminating organ is the liver, although the kidney and lung also metabolise nicotine. More than 20 metabolites of nicotine have been identified, all of which are believed to be less active than the parent compound.

The primary metabolite of nicotine in plasma, cotinine, has a half-life of 15 to 20 hours and concentrations that exceed nicotine by 10-fold.

Elimination

The average plasma clearance of nicotine is 70 l/hour and the half-life is 2-3 hours.

The primary urinary metabolites are cotinine (12% of the dose) and trans-3-hydroxy-cotinine (37% of the dose). About 10% of nicotine is excreted unchanged in the urine. As much as 30% of nicotine may be excreted unchanged in the urine with high flow rates and acidification of the urine below pH 5.

Linearity/non-linearity

There is only a small deviation from dose-linearity of AUC∞ and Cmax as shown when single doses of 1, 2, 3 and 4 sprays of the 1 mg mouth spray are given.

Characteristics in specific groups of subjects:

Renal Impairment

Progressive severity of renal impairment is associated with decreased total clearance of nicotine. Nicotine clearance was on average decreased by 50%, in subjects with severe renal impairment. Raised nicotine levels have been seen in smokers undergoing hemodialysis.

Hepatic Impairment

In smokers with liver cirrhosis but only mild liver impairment (Child-Pugh score 5) the pharmacokinetics of nicotine is unaffected. However, in smokers with moderately impaired liver (Child-Pugh score 7) total clearance has been reported to be reduced by 40-50%. There is no information available in subjects with a Child-Pugh score > 7.

Elderly

A minor reduction in total clearance of nicotine, not justifying adjustment of dosage, has been demonstrated in healthy elderly patients.

5.3 Preclinical safety data

Nicotine was positive in some *in vitro* genotoxicity tests but there are also negative results with the same test systems. Nicotine was negative in *in vivo* tests.

Animal experiments have shown that nicotine exposure results in decreased birth-weight, decreased litter size and decreased survival of offspring.

The results of carcinogenicity assays did not provide any clear evidence of a tumorigenic effect of nicotine.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Propylene glycol (E1520)
Anhydrous ethanol
Trometamol
Poloxamer 407 (containing butylated hydroxytoluene (E321))
Glycerol (E422)
Sodium hydrogen carbonate
Levomenthol
Spearmint flavour
Sucralose
Acesulfame potassium

Hydrochloric acid (for pH adjustment)
Purified water

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

2 years

6.4 Special precautions for storage

Do not store above 30°C

6.5 Nature and contents of container

PET bottle containing 13.2 ml of solution. One bottle contains at least 150 sprays. The bottle is placed in a dispenser with a mechanical spray pump.

Nicorette QuickMist Spearmint SmartTrack 1mg/spray mouthspray: Includes an inactive NFC chip on the outer of the dispenser to allow smartphone connectivity.

Pack Sizes: 1 dispenser, 2 dispensers

Not all pack sizes may be marketed.

6.6 Special precautions for disposal

Any unused product or waste material should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

McNeil Products Limited
1 Station Hill Square
Station Hill
Reading
RG1 1LN
UK

8 MARKETING AUTHORISATION NUMBER(S)

PL 15513/0416

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

23/09/2025

10 DATE OF REVISION OF THE TEXT

28 Sep 2026

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Nicorette® 15 mg Inhalator

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Nicotine 15 mg per cartridge.
For a full list of excipients see section 6.1

3 PHARMACEUTICAL FORM

Inhalation cartridge for oromucosal use.
A white to slightly coloured porous plug in a sealed, transparent plastic tube.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Nicorette Inhalator relieves and/or prevents craving and nicotine withdrawal symptoms in nicotine dependence, such as those arising from the use of tobacco or electronic cigarettes. It is indicated to aid quitting or reduction prior to quitting, to assist those who are unwilling or unable to use such products, and as a safer alternative to smoking tobacco for smokers and those around them.
Nicorette Inhalator is indicated in pregnant and lactating women making a quit attempt.

4.2 Posology and method of administration

Adults and Children over 12 years of age
Nicorette Inhalator should be used whenever the urge to smoke/vape is felt or to prevent cravings in situations where these are likely to occur.

Smokers/vapers willing or able to stop smoking/vaping immediately should initially replace all their cigarettes/e-cigarettes with the Inhalator and as soon as they are able, reduce the number of Inhalator cartridges used until they have stopped completely.

Smokers/vapers aiming to reduce cigarettes/e-cigarettes should use the Inhalator, as needed, between smoking/vaping episodes to prolong smoke/vape-free intervals and with the intention to reduce smoking/vaping as much as possible.

As soon as they are ready smokers/vapers should aim to quit smoking/vaping

completely.

Maximum daily dose: 6 cartridges.

When making a quit attempt behavioural therapy, advice and support will normally improve the success rate. Those who have quit smoking/vaping but are having difficulty discontinuing their Inhalator are recommended to contact their pharmacist or doctor for advice.

Each cartridge can be used for approximately eight 5-minute sessions, with each cartridge lasting approximately 40 minutes of intense use. The more the subject is able to use the Inhalator, the easier it will be to achieve maximum reduction of cigarettes/e-cigarettes and/or quit smoking/vaping completely.

Method of administration
The cartridge is inserted into the mouthpiece according to the instructions. When a patient draws air into the mouth through the mouthpiece, nicotine is vaporised and absorbed by the buccal mucosa. Minimal nicotine reaches the lungs. The amount of nicotine from a puff is less than that from a cigarette. To compensate for less nicotine delivery from a puff it is necessary to inhale more often than when smoking a cigarette.

The number of cartridges, frequency, puffing/inhalation time and technique does vary between individuals.
The actual time that the cartridge is active depends on the intensity of use. After about 40 minutes of intense use the maximal dose is achieved and it is about then that the nicotine amounts released from the cartridge begin to fall away, such that the cartridge is rejected by the user.

4.3 Contraindications

Hypersensitivity to any component of the Inhalator.
Nicorette Inhalator is contraindicated in children under the age of 12 years.

4.4 Special warnings and precautions for use

Any risks that may be associated with NRT are substantially outweighed by the well-established dangers of continued smoking. The risks of continued vaping are not yet established.

A risk-benefit assessment should be made by an appropriate healthcare professional for patients with the following conditions:

Underlying cardiovascular disease: In stable cardiovascular disease this product presents a lesser hazard than continuing to smoke. However dependent smokers currently hospitalised as a result of myocardial infarction, unstable or worsening angina including Prinzmetal angina, severe dysrhythmia or CVA and who are considered to be haemodynamically unstable and/or who have uncontrolled hypertension should be encouraged to stop smoking with non-pharmacological interventions. If this fails, this product may be considered, but as data on safety in this patient group are

limited, initiation should only be under medical supervision. The risks of continued vaping are not yet established.

Diabetes mellitus: Patients with diabetes mellitus should be advised to monitor their blood sugar levels more closely than usual when quitting and NRT is initiated as reductions in nicotine induced catecholamine release can affect carbohydrate metabolism.

GI disease: Nicotine may exacerbate symptoms in patients suffering from oesophagitis, gastritis or peptic ulcers and NRT preparations should be used with caution in these conditions. Ulcerative stomatitis has been reported.

Renal or hepatic impairment: This product should be used with caution in patients with moderate to severe hepatic impairment and/or severe renal impairment as the clearance of nicotine or its metabolites may be decreased with the potential for increased adverse effects.

Seizures: Potential risks and benefits of nicotine should be carefully evaluated before use in subjects with a history of epilepsy as cases of convulsions have been reported in association with nicotine.

Danger in children: Doses of nicotine tolerated by adult and adolescent smokers or vapers can produce severe toxicity in children that may be fatal. Products containing nicotine should not be left where they may be misused, handled or ingested by children. If a child swallows, chews or sucks on the Inhalator cartridge (used as well as unused) there is a risk of poisoning in the child.

Phaeochromocytoma and uncontrolled hyperthyroidism: As nicotine causes release of catecholamines, this product should be used with caution in patients with uncontrolled hyperthyroidism or phaeochromocytoma.

Transferred dependence: Transferred dependence is rare and is both less harmful and easier to break than smoking dependence.

Stopping smoking: Polycyclic aromatic hydrocarbons in tobacco smoke induce the metabolism of drugs metabolised by CYP 1A2 (and possibly by CYP 1A1). When a smoker stops smoking, this may result in slower metabolism and a consequent rise in blood levels of such drugs. This is of potential clinical importance for products with a narrow therapeutic window, e.g. theophylline, clozapine and ropinirole.

Lung Disease: Patients with obstructive lung disease may find use of the Inhalator difficult. Nicotine mouth spray, gum, patch, nasal spray or sublingual tablet may be preferred in such cases. This product should be used with caution in patients with chronic throat disease and bronchospastic disease.

Allergic reactions: Susceptibility to angioedema and urticaria.

Potential choking hazard: This product contains some small parts. Any unused

cartridges should remain in the cartridge tray to minimise the risk of swallowing.

4.5 Interaction with other medicinal products and other forms of interaction

No clinically relevant interactions between nicotine replacement therapy and other drugs have definitely been established. However nicotine may possibly enhance the haemodynamic effects of adenosine i.e. increase in blood pressure and heart rate and also increase pain response (angina-pectoris type chest pain) provoked by adenosine administration.

4.6 Fertility, pregnancy and lactation

Pregnancy
Stopping smoking is the single most effective intervention for improving the health of both the pregnant smoker and her baby, and the earlier abstinence is achieved the better. Ideally smoking cessation during pregnancy should be achieved without NRT. Nicotine passes to the foetus and affects its breathing movements and circulation. The effect on the circulation is dose-dependent. However, if the mother cannot (or is considered unlikely to) quit without pharmacological support, NRT may be used as the risk to the foetus is lower than that expected with smoking tobacco. Stopping completely is by far the best option but if this is not achievable this product may be used in pregnancy as a safer alternative to smoking. Because of the potential for nicotine-free periods, intermittent dose forms are preferable, but patches may be considered as an alternative if there is significant nausea and/or vomiting. If patches are used they should, if possible, be removed at night when the foetus would not normally be exposed to nicotine.

There is no or limited data regarding the effect of vaping in pregnancy.

Use of NRT by the pregnant smoker/vaper should only be initiated after advice from a health care professional.

Lactation
Nicotine should be avoided during breast-feeding. The relatively small amounts of nicotine found in breast milk during NRT use are less hazardous to the infant than second-hand smoke. Intermittent dose forms would minimize the amount of nicotine in breast milk and permit feeding when levels were at their lowest.

There is no or limited data regarding the effect of vaping in lactating women.

Use of NRT by breast feeding smokers/vapers should only be initiated after advice from a health care professional. Women should take the product as soon as possible after breastfeeding.

Fertility
In females tobacco smoking delays time to conception, decreases in-vitro fertilization success rates, and significantly increases the risk of infertility.

In males tobacco smoking reduces sperm production, increases oxidative

stress, and DNA damage. Spermatozoa from smokers have reduced fertilizing capacity.

The specific contribution of nicotine to these effects in humans is unknown. There is no or limited data regarding the effect of vaping on fertility.

4.7 Effects on ability to drive and use machines

This medicinal product has no or negligible influence on the ability to drive and use machines.

4.8 Undesirable effects

Effects of Smoking Cessation
Some symptoms may be related to nicotine withdrawal associated with stopping smoking. These can include irritability/aggression, dysphoria/depressed mood, anxiety, restlessness, poor concentration, increased appetite/weight gain, urges to smoke (cravings), night-time awakenings/sleep disturbance, decreased heart rate, dizziness, presyncopal symptoms, cough, constipation, gingival bleeding or nasopharyngitis.
Increased frequency of aphthous ulcer may occur after abstinence from smoking. The causality is unclear.

Effects of Vaping Cessation
The nicotine withdrawal effects of vaping cessation have not been established; however it is anticipated that many of the effects relating to nicotine withdrawal will be the same as those seen with tobacco smoking cessation.

Adverse Drug Reactions
This product may cause adverse reactions similar to those associated with nicotine given by other means, including smoking and vaping, and these are mainly dose-dependent. At recommended doses this product has not been found to cause any serious adverse effects. Excessive use of Nicorette Inhalator by those who have not been in the habit of inhaling tobacco smoke/vaping could possibly lead to nausea, faintness or headaches.

Most of the undesirable effects reported by the patient occur during the first weeks after starting treatment. About 40% of users experience mild local reactions such as cough and irritation in the mouth and throat however most subjects adapt to this with ongoing use.
Allergic reactions (including symptoms of anaphylaxis) can occur during the use of this product.

The adverse reactions observed in patients treated with oral nicotine formulations during clinical trials and post-marketing experience are listed below by system organ class (SOC).

Frequencies are defined in accordance with current guidance, as: very common (≥1/10); common (≥1/100, <1/10); uncommon (≥1/1 000, <1/100); rare (≥1/10 000, <1/1 000); very rare (<1/10 000), not known - cannot be estimated from the available data.

System Organ Class	Reported Adverse Event	Incidence
Immune System Disorders	Hypersensitivity[a] Anaphylactic reaction[a]	Common Not known
Psychiatric Disorders	Abnormal dreams[c]	Uncommon
Nervous System Disorders	Headache[a#] Burning sensation* Dizziness Dysgeusia Paraesthesia[a] Seizures	Very common Common Common Common Common Not known
Eye Disorders	Blurred vision Lacrimation increased	Not known Not known
Cardiac Disorders	Palpitations[a] Tachycardia[a] Atrial fibrillation	Uncommon Uncommon Very rare
Vascular Disorders	Flushing[a] Hypertension[a]	Uncommon Uncommon
Respiratory, Thoracic and Mediastinal Disorders	Cough** Throat irritation** Nasal congestion Bronchospasm Dysphonia Dyspnoea[a] Sneezing Throat tightness	Common Very common Common Uncommon Uncommon Uncommon Uncommon Uncommon
Gastrointestinal Disorders	Nausea[a] Stomatitis Hiccups[****] Abdominal pain Diarrhoea[***] Dry mouth Dyspepsia Flatulence Salivary hypersecretion Vomiting[a] Eructation Glossitis Oral mucosal blistering and exfoliation Paraesthesia oral[***] Dysphagia Hypoaesthesia oral[***] Retching Dry throat Gastrointestinal discomfort[a] Lip pain	Very common Very common Very common Common Common Common Common Common Common Common Uncommon Uncommon Uncommon Uncommon Rare Rare Rare Not known Not known Not known
Skin and Subcutaneous Tissue Disorders	Hyperhidrosis[a] Pruritus[a] Rash[a] Urticaria[a]	Uncommon Uncommon Uncommon

	Angioedema[a] Erythema[a]	Uncommon Not known Not known
Musculoskeletal and Connective Tissue Disorders	Pain in Jaw[b] Muscle tightness[b]	Uncommon Not known
General Disorders and Administration Site Conditions	Fatigue[a] Asthenia[a] Chest discomfort and pain[a] Malaise[a]	Common Uncommon Uncommon Uncommon

a Systemic effects; b Tightness of jaw and pain in jaw with nicotine gum formulation
c Identified only for formulations applied during the night
* At the application site
**Higher frequency observed in clinical studies with inhaler formulation.
***Reported the same or less frequently than placebo
**** Higher frequency observed in clinical studies with mouth spray formulation
# Although the frequency in the active group is less than that of the placebo group, the frequency in the specific formulation in which the PT was identified as a systemic ADR was greater in the active group than the placebo group.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

4.9 Overdose

Symptoms: Symptoms of overdose with nicotine from this product may occur in smokers/vapers who have previously had a low nicotine intake from cigarettes/e-cigarettes if other sources of nicotine are used concomitantly with this product.
Acute or chronic toxicity of nicotine in man is highly dependent on mode and route of administration. Adaptation to nicotine (e.g. in smokers/vapers) is known to significantly increase tolerability compared with non-smokers/vapers. The minimum lethal dose of nicotine in a non-tolerant man has been estimated to be 40 to 60 mg. Symptoms of acute nicotine poisoning include nausea, vomiting, increased salivation, abdominal pain, diarrhoea, sweating, headache, dizziness, disturbed hearing and marked weakness. In extreme cases, these symptoms may be followed by hypotension, rapid or weak or irregular pulse, breathing difficulties, prostration, circulatory collapse and terminal convulsions.

Management of an overdose: All nicotine in-take should stop immediately and the patient should be treated symptomatically. Artificial respiration should be instituted if necessary. Activated charcoal reduces the gastro-intestinal absorption of nicotine.

Doses of nicotine that are tolerated by adult smokers/vapers during treatment may produce severe symptoms of poisoning in children and may prove fatal.

Suspected nicotine poisoning in a child should be considered a medical emergency and treated immediately.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic Group: Drug for treatment of addiction.
ATC Code: N07B A01

Nicorette Inhalator facilitates uptake of nicotine through the buccal mucosa into the venous circulation. The amount taken up alleviates the craving symptoms caused by the absence of nicotine from smoking/vaping. Increased appetite is a recognised symptom of nicotine withdrawal and post-cessation weight gain is common. Clinical trials have demonstrated that Nicotine Replacement Therapy can help control weight following a quit attempt.

5.2 Pharmacokinetic properties

The following information is based on data derived from Nicorette 10 mg Inhalator:

Nicotine given intravenously has a volume of the distribution of 2 or 3 l/kg with a half-life of 1-2 hours. Average plasma clearance is about 1-2 l/min mainly in the liver. More than 20 metabolites are known, all less active than nicotine: cotinine, with a half life of 15-20 hours and concentrations ten times that of nicotine is the main one.

Plasma binding of nicotine below 5% means significant displacement of drugs or nicotine is unlikely. Nicotine is excreted in the urine principally as cotinine (15%), 3-hydroxycotinine (45%), nicotine (10%).

Most inhaled nicotine is absorbed via the buccal mucosa. Forced rapid inhalation over 20 minutes, results in a wide range of nicotine doses (1.3-6.2 mg). On average 2 mg of nicotine is released during 20 minutes of intensive use. Uptake is slow and free of the peaks resultant from cigarette smoking. In normal use, plasma levels of 6-8ng/ml nicotine are obtained – about one third that from smoking, which is equivalent to an hourly 2 mg nicotine chewing gum.

When used like a cigarette the inhalator on average delivers 1 mg in 80 puffs (e.g. 8 puffs per minute for 10 minutes). When used in this way this results in, a degree of nicotine substitution of about 50% compared to hourly smoking. Peak plasma levels occur within 15 minutes after the end of inhalation. Forced rapid inhalation for 20 minutes per hour for 12 hours achieved steady state plasma levels of 20-25ng/ml.

Ambient temperature affects volatilisation of nicotine, the biologically available dose rising by 35% for each 10□C above 20□C. Use below 15□C is not recommended.

Because the pattern of use if decided by the patient up to a limit of 6 cartridges per day to relieve craving, therapeutic levels of nicotine are individual, dictated by the level of dependence.

5.3 Preclinical safety data

None stated.

6 PHARMACEUTICAL PARTICULARS

6.1 List of Excipients

Levomenthol
Porous plug of polyethylene

6.2 Incompatibilities

Not applicable

6.3 Shelf life

36 months.
Once inserted into the mouthpiece the cartridge should be disposed of within 48 hours even if it has not been used.

6.4 Special precautions for storage

Store below 25°C.

This product works best at room temperature. In cold conditions (below 15°C) the nicotine evaporates less readily and it will be necessary to inhale more frequently, whilst in warm conditions (above 30□C) nicotine will evaporate more readily and inhalation should be less frequent to avoid overdose.

6.5 Nature and contents of container

Polypropylene mouthpiece with acrylonitrile / methacrylate copolymer cartridges containing polyethylene porous plugs with polyester / aluminium foil seals.

The cartridges are provided in a PVC tray which is sealed with aluminium foil.

Pack sizes:
4 cartridges with 1 inhalator mouthpiece
20 cartridges with 1 inhalator mouthpiece

36 cartridges with 1 inhalator mouthpiece

Not all pack sizes may be marketed.

6.6 Special precautions for disposal

Potential choking hazard: This product contains some small parts. Any unused cartridges should remain in the cartridge tray to minimise the risk of swallowing.

Because of residual nicotine, used cartridges may be a hazard to children, animals and fish and so should never be thrown away or left lying around. They should be kept in the case and disposed of with household rubbish.

7 MARKETING AUTHORISATION HOLDER

McNeil Products Limited
50 – 100 Holmers Farm Way
High Wycombe
Buckinghamshire
HP12 4EG
UK

8 MARKETING AUTHORISATION NUMBER(S)

PL 15513/0358

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

03/06/2011

10 DATE OF REVISION OF THE TEXT

27/01/2026

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Nicorette 2 mg Gum

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Chewing Gum containing 2 mg nicotine, as nicotine resinate.

Excipients with known effect:
Butylated hydroxytoluene
Sorbitol

For a full list of excipients see section 6.1

3 PHARMACEUTICAL FORM

Chewing Gum

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Nicorette 2 mg Gum relieves and/or prevents craving and nicotine withdrawal symptoms in nicotine dependence, such as those arising from the use of tobacco or electronic cigarettes. It is indicated to aid quitting or reduction prior to quitting, to assist those who are unwilling or unable to use such products, and as a safer alternative to smoking tobacco for smokers and those around them.

Nicorette 2 mg Gum is indicated in pregnant and lactating women making a quit attempt.

4.2 Posology and method of administration

Adults and children over 12 years of age
Nicorette 2 mg Gum should be chewed slowly according to the instructions. The strength of gum to be used will depend on the smoking/vaping habits of the individual. In general, if the patient smokes 20 or less cigarettes a day, 2 mg nicotine gum is indicated. If more than 20 cigarettes per day are smoked, 4 mg nicotine gum will be needed to meet the withdrawal of the high serum nicotine levels from heavy smoking.

Light to moderate vapers (e.g. vape infrequently or use low strength e-liquid) should start with 2 mg nicotine gum. If the 2 mg nicotine gum does not relieve the urge to vape, 4 mg nicotine gum should be used. Heavy vapers (e.g. vape frequently or use high strength e-liquid) should use 4 mg nicotine gum.

Nicorette 2 mg Gum should be used whenever the urge to smoke or vape is felt or to prevent cravings in situations where these are likely to occur.

Patients willing or able to stop smoking/vaping immediately should initially replace all their cigarettes/e-cigarettes with the gum and as soon as they are able, reduce the number of gums used until they have stopped completely.

Patients aiming to reduce cigarettes/e-cigarettes should use Nicorette 2 mg Gum between smoking/vaping episodes, as needed, to prolong smoke/vape-free intervals and to reduce their use as much as possible.

As soon as they are ready patients should aim to quit smoking /vaping completely.

Maximum daily dose: 15 pieces per day.

When making a quit attempt behavioural therapy, advice and support will normally improve the success rate. Those who have quit smoking/vaping but are having difficulty discontinuing Nicorette 2 mg Gum are recommended to contact their pharmacist or doctor for advice.

For those using the 4 mg gum, switching to the 2 mg gum may be helpful when stopping treatment or reducing the number of gums used each day.

The chewing gums should be used whenever there is an urge to smoke/vape according to the "chew and rest" technique described on the pack. After about 30 minutes of such use, the gum will be exhausted. Absorption of nicotine is through the buccal mucosa, any nicotine which is swallowed being destroyed by the liver.

4.3 Contraindications

Hypersensitivity to nicotine or any component of the chewing gum.

Nicorette 2 mg Gum is contraindicated in children under the age of 12 years.

4.4 Special warnings and precautions for use

Any risks that may be associated with NRT are substantially outweighed by the well-established dangers of continued smoking. The risks of continued vaping are not yet established.

A risk-benefit assessment should be made by an appropriate healthcare professional for patients with the following conditions:

Underlying cardiovascular disease: In stable cardiovascular disease this product presents a lesser hazard than continuing to smoke. However dependent smokers currently hospitalised as a result of myocardial infarction, unstable or worsening angina including Prinzmetal angina, severe dysrhythmia or CVA and who are considered to be haemodynamically unstable and/or who suffer with uncontrolled hypertension should be

encouraged to stop smoking with non-pharmacological interventions. If this fails, this product may be considered, but as data on safety in this patient group are limited, initiation should only be under medical supervision. The risks of continued vaping are not yet established.

Diabetes mellitus: Patients with diabetes mellitus should be advised to monitor their blood sugar levels more closely than usual when quitting and NRT is initiated as reductions in nicotine induced catecholamine release can affect carbohydrate metabolism.

GI disease: Nicotine may exacerbate symptoms in patients suffering from oesophagitis, gastritis or peptic ulcers and NRT preparations should be used with caution in these conditions. Ulcerative stomatitis has been reported.

Seizures: Potential risks and benefits of nicotine should be carefully evaluated before use in subjects with a history of epilepsy as cases of convulsions have been reported in association with nicotine.

Renal or hepatic impairment: This product should be used with caution in patients with moderate to severe hepatic impairment and/or severe renal impairment as the clearance of nicotine or its metabolites may be decreased with the potential for increased adverse effects.

Danger in children: Doses of nicotine tolerated by adult and adolescent smokers or vapers can produce severe toxicity in children that may be fatal. Products containing nicotine should not be left where they may be misused, handled or ingested by children. Nicotine gum should be disposed of with care.

Phaeochromocytoma and uncontrolled hyperthyroidism: As nicotine causes release of catecholamines, this product should be used with caution in patients with uncontrolled hyperthyroidism or phaeochromocytoma.

Transferred dependence: Transferred dependence is rare and is both less harmful and easier to break than smoking dependence.

Stopping smoking: Polycyclic aromatic hydrocarbons in tobacco smoke induce the metabolism of drugs metabolised by CYP 1A2 (and possibly by CYP 1A1). When a smoker stops smoking, this may result in slower metabolism and a consequent rise in blood levels of such drugs. This is of potential clinical importance for products with a narrow therapeutic window, e.g. theophylline, clozapine and ropinirole.

Excipients: This product contains sorbitol; patients with rare hereditary problems of fructose intolerance should not take this medicine.
This product also contains butylated hydroxy toluene (E321); this may cause local skin reactions (e.g. contact dermatitis), or irritation to the eyes and mucous membranes.

This product contains 0.616 mg of alcohol (ethanol) in each gum. The small amount of alcohol in this medicine will not have any noticeable effects.

This medicine contains less than 1 mmol sodium (23 mg) in each chewing gum, that is to say essentially 'sodium- free'.

Denture warning: Patients who wear dentures may experience difficulty in chewing this product. The chewing gum may stick to and may in rare cases damage dentures.

4.5 Interaction with other medicinal products and other forms of interactions

No clinically relevant interactions between nicotine replacement therapy and other drugs have definitely been established. However nicotine may possibly enhance the haemodynamic effects of adenosine i.e. increase in blood pressure and heart rate and also increase pain response (angina-pectoris type chest pain) provoked by adenosine administration.

4.6 Fertility, pregnancy and lactation

Pregnancy

Stopping smoking is the single most effective intervention for improving the health of both the pregnant smoker and her baby, and the earlier abstinence is achieved the better. Ideally smoking cessation during pregnancy should be achieved without NRT. Nicotine passes to the foetus and affects its breathing movements and circulation. The effect on the circulation is dose-dependent. However, if the mother cannot (or is considered unlikely to) quit without pharmacological support, NRT may be used as the risk to the foetus is lower than that expected with smoking tobacco. Stopping completely is by far the best option but if this is not achievable this product may be used in pregnancy as a safer alternative to smoking. Because of the potential for nicotine-free periods, intermittent dose forms are preferable, but patches may be considered as an alternative if there is significant nausea and/or vomiting. If patches are used they should, if possible, be removed at night when the foetus would not normally be exposed to nicotine.

There is no or limited data regarding the effect of vaping in pregnancy.

Use of NRT by the pregnant smoker/vaper should only be initiated after advice from a health care professional.

Lactation

Nicotine should be avoided during breast-feeding. The relatively small amounts of nicotine found in breast milk during NRT use are less hazardous to the infant than second-hand smoke. Intermittent dose forms would minimize the amount of nicotine in breast milk and permit feeding when levels were at their lowest.

There is no or limited data regarding the effect of vaping in lactating women.

Use of NRT by breast feeding smokers/vapers should only be initiated after advice from a health care professional. Women should use the product as soon

as possible after breastfeeding.

Fertility
In females tobacco smoking delays time to conception, decreases in-vitro fertilization success rates, and significantly increases the risk of infertility.

In males tobacco smoking reduces sperm production, increases oxidative stress, and DNA damage. Spermatozoa from smokers have reduced fertilizing capacity.

The specific contribution of nicotine to these effects in humans is unknown.

There is no or limited data regarding the effect of vaping on fertility.

4.7 Effects on ability to drive and use machines
This product has no or negligible influence on the ability to drive and use machines.

4.8 Undesirable effects
Effects of Smoking Cessation
Some symptoms may be related to nicotine withdrawal associated with stopping smoking. These can include irritability/aggression, dysphoria/depressed mood, anxiety, restlessness, poor concentration, increased appetite/weight gain, urges to smoke (cravings), night-time awakenings/sleep disturbance, decreased heart rate, dizziness, presyncopal symptoms, cough, constipation, gingival bleeding or nasopharyngitis.

Increased frequency of aphthous ulcer may occur after abstinence from smoking. The causality is unclear.

Effects of Vaping Cessation
The nicotine withdrawal effects of vaping cessation have not been established; however it is anticipated that many of the effects relating to nicotine withdrawal will be the same as those seen with tobacco smoking cessation.

Adverse Drug Reactions
This product may cause adverse reactions similar to those associated with nicotine given by other means, including smoking and vaping, and these are mainly dose-dependent. At recommended doses this product has not been found to cause any serious adverse effects. Most of the undesirable effects reported by the patients occur during the first 3-4 weeks after start of treatment.

Excessive consumption of this product by those who have not been in the habit of inhaling tobacco smoke or vaping could possibly lead to nausea, faintness or headaches. Excessive swallowing of dissolved nicotine may, at first, cause hiccupping.

Nicotine from the gum may sometimes cause a slight irritation of the throat at

the start of treatment however most subjects adapt to this with ongoing use. This product may also cause increased salivation.

Allergic reactions (including symptoms of anaphylaxis) can occur during the use of the product.

Those who are prone to indigestion may suffer initially from minor degrees of indigestion or heartburn if the 4 mg nicotine gum is used; slower chewing and the use of the 2 mg nicotine gum (if necessary more frequently) will usually overcome this problem.

The chewing gum may stick to and may in rare cases damage dentures.

The adverse reactions observed in patients treated with oral nicotine formulations during clinical trials and post-marketing experience are listed below by system organ class (SOC). Frequencies are defined in accordance with current guidance, as: very common (>1/10); common (>1/100, <1/10); uncommon (>1/1 000, <1/100); rare (>1/10 000, <1/1 000); very rare (<1/10 000), not known - cannot be estimated from the available data.

System Organ Class	**Reported Adverse Event**	**Incidence**
Immune System Disorders	Hypersensitivity[a] Anaphylactic reaction[a]	Common Not known
Psychiatric Disorders	Abnormal dreams[*]	Uncommon
Nervous System Disorders	Headache[a#] Burning sensation[c] Dizziness Dysgeusia Paraesthesia[a] Seizures	Very common Common Common Common Common Not known
Eye Disorders	Blurred vision Lacrimation increased	Not known Not known
Cardiac Disorders	Palpitations[a] Tachycardia[a] Atrial fibrillation	Uncommon Uncommon Very rare
Vascular Disorders	Flushing[a] Hypertension[a]	Uncommon Uncommon
Respiratory, Thoracic and Mediastinal Disorders	Cough** Throat irritation** Bronchospasm Dysphonia Dyspnoea[a] Nasal congestion Sneezing Throat tightness	Common Very common Uncommon Uncommon Uncommon Uncommon Uncommon Uncommon

Gastrointestinal Disorders	Nausea[a] Hiccups**** Abdominal pain Diarrhoea*** Dry mouth Flatulence Salivary hypersecretion	Very common Very common Common Common Common Common Common

	Stomatitis Vomiting[a] Dyspepsia Eructation Glossitis Oral mucosal blistering and exfoliation Paraesthesia oral[***] Dysphagia Hypoaesthesia oral[***] Retching Dry throat Gastrointestinal discomfort[a] Lip pain	Common Common Common Uncommon Uncommon Uncommon Uncommon Rare Rare Rare Not known Not known Not known
Skin and Subcutaneous Tissue Disorders	Urticaria[a] Hyperhidrosis[a] Pruritus[a] Rash[a] Erythema[a]	Uncommon Uncommon Uncommon Uncommon Not known
Musculoskeletal and Connective Tissue Disorders	Pain in jaw[b] Muscle tightness[b]	Uncommon Not known
General Disorders and Administration Site Conditions	Fatigue[a] Asthenia[a] Chest discomfort and pain[a] Malaise[a] Allergic reactions including angioedema	Common Uncommon Uncommon Uncommon Rare

[a] Systemic effects; [b] Tightness of jaw and pain in jaw with nicotine gum formulation
[c] At the application site
[*]Identified only for formulations applied during the night
[**]Higher frequency observed in clinical studies with inhaler formulation.
***Reported the same or less frequently than placebo
**** Higher frequency observed in clinical studies with mouth spray formulation
[#] Although the frequency in the active group is less than that of the placebo group, the frequency in the specific formulation in which the PT was identified as a systemic ADR was greater in the active group than the placebo group

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

4.9 Overdose

Symptoms: Symptoms of overdose with nicotine from this product may occur in smokers/vapers who have previously had a low nicotine intake from cigarettes/e-cigarettes or if other sources of nicotine are used concomitantly

with this product.

Acute or chronic toxicity of nicotine in man is highly dependent on mode and route of administration. Adaptation to nicotine (e.g. in smokers/vapers) is known to significantly increase tolerability compared with non-smokers/vapers. The minimum lethal dose of nicotine in a non-tolerant man has been estimated to be 40 to 60 mg. Symptoms of acute nicotine poisoning include nausea, vomiting, increased salivation, abdominal pain, diarrhoea, sweating, headache, dizziness, disturbed hearing and marked weakness. In extreme cases, these symptoms may be followed by hypotension, rapid or weak or irregular pulse, breathing difficulties, prostration, circulatory collapse and terminal convulsions.

Management of an overdose: All nicotine intake should stop immediately and the patient should be treated symptomatically. Artificial respiration should be instituted if necessary. Activated charcoal reduces the gastro-intestinal absorption of nicotine.

The risk of poisoning as a result of swallowing the gum is very small, as absorption in the absence of chewing is slow and incomplete.

Doses of nicotine that are tolerated by adult smokers/vapers during treatment may produce severe symptoms of poisoning in children and may prove fatal. Suspected nicotine poisoning in a child should be considered a medical emergency and treated immediately.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Drugs used in nicotine dependence
ATC code: N07B A01

The pharmacological effects of nicotine are well documented. Those resulting from chewing Nicorette 2 mg Gum are comparatively small. The response at any one time represents a summation of stimulant and depressant actions from direct, reflex and chemical mediator influences on several organs. The main pharmacological actions are central stimulation and/or depression; transient hyperpnoea; peripheral vasoconstriction (usually associated with a rise in systolic pressure); suppression of appetite and stimulation of peristalsis. Increased appetite is a recognised symptom of nicotine withdrawal and post-cessation weight gain is common. Clinical trials have demonstrated that Nicotine Replacement Therapy can help control weight following a quit attempt.

5.2 Pharmacokinetic properties

Nicotine administered in chewing gums is readily absorbed from the buccal mucous membranes. Demonstrable blood levels are obtained within 5 – 7 minutes and reach a maximum about 30 minutes after the start of chewing.

Blood levels are roughly proportional to the amount of nicotine chewed and have been shown never to exceed those obtained from smoking cigarettes.

5.3 Preclinical safety data

Preclinical data indicate that nicotine is neither mutagenic nor genotoxic. There are no other findings derived from preclinical testing of relevance to the prescriber in determining the safety of the product which have not been considered in other relevant sections of this Summary of Product Characteristics.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Polacrilin
Chewing gum base, containing butylated hydroxy toluene (E321)
Sorbitol
Sodium carbonate, anhydrous
Sodium bicarbonate
Flavour for smoker (contains ethanol)
Haverstroo flavour
Glycerol
Talcum

6.2 Incompatibilities

Not applicable

6.3 Shelf life

30 months

6.4 Special precautions for storage

Do not store above 25ºC.

6.5 Nature and contents of container

PVC/PVDC/Al Blister packed strips each containing 15 pieces supplied in packs of 15, 30, 75, 105, 165 and 210 pieces. Pack containing blister strip of 6 pieces.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal and handling

Dispose of Nicorette Gum sensibly.
Any unused product or waste material should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

McNeil Products Limited
1 Station Hill Square
Station Hill
Reading
RG1 1LN
UK

8 MARKETING AUTHORISATION NUMBER(S)

PL 15513/0169

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

24/01/2008

10 DATE OF THE REVISION OF THE TEXT

29 September 2026

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Nicorette 4 mg Gum

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Chewing Gum containing 4 mg nicotine, as nicotine resinate.

Excipients with known effect:
Butylated hydroxytoluene
Sorbitol

For a full list of excipients see section 6.1

3 PHARMACEUTICAL FORM

Chewing Gum

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Nicorette 4 mg Gum relieves and/or prevents craving and nicotine withdrawal symptoms in nicotine dependence, such as those arising from the use of tobacco or electronic cigarettes. It is indicated to aid quitting or reduction prior to quitting, to assist those who are unwilling or unable to use such products, and as a safer alternative to smoking tobacco for smokers and those around them.

Nicorette 4 mg Gum is indicated in pregnant and lactating women making a quit attempt.

4.2 Posology and method of administration

Adults and children over 12 years of age
Nicorette 4 mg Gum should be chewed slowly according to the instructions.

The strength of gum to be used will depend on the smoking/vaping habits of the individual. In general, if the patient smokes 20 or less cigarettes a day, 2 mg nicotine gum is indicated. If more than 20 cigarettes per day are smoked, 4 mg nicotine gum will be needed to meet the withdrawal of the high serum nicotine levels from heavy smoking.

Light to moderate vapers (e.g. vape infrequently or use low strength e-liquid) should start with 2 mg nicotine gum. If the 2 mg nicotine gum does not relieve the urge to vape, 4 mg nicotine gum should be used. Heavy vapers (e.g. vape frequently or use high strength e-liquid) should use 4 mg nicotine gum.

Nicorette 4 mg Gum should be used whenever the urge to smoke or vape is felt or to prevent cravings in situations where these are likely to occur.

Patients willing or able to stop smoking/vaping immediately should initially replace all their cigarettes/e-cigarettes with the gum and as soon as they are able, reduce the number of gums used until they have stopped completely.

Patients aiming to reduce cigarettes/e-cigarettes should use Nicorette 4mg Gum, between smoking/vaping episodes, as needed, to prolong smoke/vape-free intervals and to reduce their use as much as possible.

As soon as they are ready patients should aim to quit smoking/vaping completely.

Maximum daily dose: 15 pieces per day.

When making a quit attempt behavioural therapy, advice and support will normally improve the success rate. Those who have quit smoking/vaping but are having difficulty discontinuing Nicorette 4 mg Gum are recommended to contact their pharmacist or doctor for advice.

For those using the 4 mg gum, switching to the 2 mg gum may be helpful when stopping treatment or reducing the number of gums used each day**.**

The chewing gums should be used whenever there is an urge to smoke/vape according to the "chew and rest" technique described on the pack. After about 30 minutes of such use, the gum will be exhausted. Absorption of nicotine is through the buccal mucosa, any nicotine which is swallowed being destroyed by the liver.

4.3 Contraindications

Hypersensitivity to nicotine or any component of the chewing gum.

Nicorette 4 mg Gum is contraindicated in children under the age of 12 years.

4.4 Special warnings and precautions for use

Any risks that may be associated with NRT are substantially outweighed by the well-established dangers of continued smoking. The risks of continued vaping are not yet established.

A risk-benefit assessment should be made by an appropriate healthcare professional for patients with the following conditions:

Underlying cardiovascular disease: In stable cardiovascular disease this product presents a lesser hazard than continuing to smoke. However dependent smokers currently hospitalised as a result of myocardial infarction, unstable or worsening angina including Prinzmetal angina, severe dysrhythmia or CVA and who are considered to be haemodynamically unstable and/or who

suffer with uncontrolled hypertension should be encouraged to stop smoking with non-pharmacological interventions. If this fails, this product may be considered, but as data on safety in this patient group are limited, initiation should only be under medical supervision. The risks of continued vaping are not yet established.

Diabetes mellitus: Patients with diabetes mellitus should be advised to monitor their blood sugar levels more closely than usual when quitting and NRT is initiated as reductions in nicotine induced catecholamine release can affect carbohydrate metabolism.

GI disease: Nicotine may exacerbate symptoms in patients suffering from oesophagitis, gastritis or peptic ulcers and NRT preparations should be used with caution in these conditions. Ulcerative stomatitis has been reported.

Seizures: Potential risks and benefits of nicotine should be carefully evaluated before use in subjects with a history of epilepsy as cases of convulsions have been reported in association with nicotine.

Renal or hepatic impairment: This product should be used with caution in patients with moderate to severe hepatic impairment and/or severe renal impairment as the clearance of nicotine or its metabolites may be decreased with the potential for increased adverse effects.

Danger in children: Doses of nicotine tolerated by adult and adolescent smokers or vapers can produce severe toxicity in children that may be fatal. Products containing nicotine should not be left where they may be misused, handled or ingested by children. Nicotine gum should be disposed of with care.

Phaeochromocytoma and uncontrolled hyperthyroidism: As nicotine causes release of catecholamines, this product should be used with caution in patients with uncontrolled hyperthyroidism or phaeochromocytoma.

Transferred dependence: Transferred dependence is rare and is both less harmful and easier to break than smoking dependence.

Stopping smoking: Polycyclic aromatic hydrocarbons in tobacco smoke induce the metabolism of drugs metabolised by CYP 1A2 (and possibly by CYP 1A1). When a smoker stops smoking, this may result in slower metabolism and a consequent rise in blood levels of such drugs. This is of potential clinical importance for products with a narrow therapeutic window, e.g. theophylline, clozapine and ropinirole.

Excipients: This product contains sorbitol; patients with rare hereditary problems of fructose intolerance should not take this medicine.
This product also contains butylated hydroxy toluene (E321); this may cause local skin reactions (e.g. contact dermatitis), or irritation to the eyes and mucous membranes.

This product contains 0.616 mg of alcohol (ethanol) in each gum. The small amount of alcohol in this medicine will not have any noticeable effects.

This medicine contains less than 1 mmol sodium (23 mg) in each chewing gum, that is to say essentially 'sodium- free'.

Denture warning: Patients who wear dentures may experience difficulty in chewing this product. The chewing gum may stick to and may in rare cases damage dentures.

4.5 Interaction with other medicinal products and other forms of interactions

No clinically relevant interactions between nicotine replacement therapy and other drugs have definitely been established. However nicotine may possibly enhance the haemodynamic effects of adenosine i.e. increase in blood pressure and heart rate and also increase pain response (angina-pectoris type chest pain) provoked by adenosine administration.

4.6 Fertility, pregnancy and lactation

Pregnancy

Stopping smoking is the single most effective intervention for improving the health of both the pregnant smoker and her baby, and the earlier abstinence is achieved the better. Ideally smoking cessation during pregnancy should be achieved without NRT. Nicotine passes to the foetus and affects its breathing movements and circulation. The effect on the circulation is dose-dependent. However, if the mother cannot (or is considered unlikely to) quit without pharmacological support, NRT may be used as the risk to the foetus is lower than that expected with smoking tobacco. Stopping completely is by far the best option but if this is not achievable this product may be used in pregnancy as a safer alternative to smoking. Because of the potential for nicotine-free periods, intermittent dose forms are preferable, but patches may be considered as an alternative if there is significant nausea and/or vomiting. If patches are used they should, if possible, be removed at night when the foetus would not normally be exposed to nicotine.

There is no or limited data regarding the effect of vaping in pregnancy.

Use of NRT by the pregnant smoker/vaper should only be initiated after advice from a health care professional.

Lactation

Nicotine should be avoided during breast-feeding. The relatively small amounts of nicotine found in breast milk during NRT use are less hazardous to the infant than second-hand smoke. Intermittent dose forms would minimize the amount of nicotine in breast milk and permit feeding when levels were at their lowest.

There is no or limited data regarding the effect of vaping in lactating women

Use of NRT by breast feeding smokers/vapers should only be initiated after advice from a health care professional. Women should use the product as soon as possible after breastfeeding.

Fertility
In females tobacco smoking delays time to conception, decreases in-vitro fertilization success rates, and significantly increases the risk of infertility.

In males tobacco smoking reduces sperm production, increases oxidative stress, and DNA damage. Spermatozoa from smokers have reduced fertilizing capacity.

The specific contribution of nicotine to these effects in humans is unknown.

There is no or limited data regarding the effect of vaping on fertility.

4.7 Effects on ability to drive and use machines
This product has no or negligible influence on the ability to drive and use machines.

4.8 Undesirable effects
Effects of Smoking Cessation
Some symptoms may be related to nicotine withdrawal associated with stopping smoking. These can include irritability/aggression, dysphoria/depressed mood, anxiety, restlessness, poor concentration, increased appetite/weight gain, urges to smoke (cravings), night-time awakenings/sleep disturbance, decreased heart rate dizziness, presyncopal symptoms, cough, constipation, gingival bleeding or nasopharyngitis.

Increased frequency of aphthous ulcer may occur after abstinence from smoking. The causality is unclear.

Effects of Vaping Cessation
The nicotine withdrawal effects of vaping cessation have not been established; however it is anticipated that many of the effects relating to nicotine withdrawal will be the same as those seen with tobacco smoking cessation.

Adverse Drug Reactions
This product may cause adverse reactions similar to those associated with nicotine given by other means, including smoking and vaping, and these are mainly dose-dependent. At recommended doses this product has not been found to cause any serious adverse effects. Most of the undesirable effects reported by the patients occur during the first 3-4 weeks after start of treatment.

Excessive consumption of this product by those who have not been in the habit of inhaling tobacco smoke or vaping could possibly lead to nausea,

faintness or headaches. Excessive swallowing of dissolved nicotine may, at first, cause hiccupping.

Nicotine from the gum may sometimes cause a slight irritation of the throat at the start of treatment however most subjects adapt to this with ongoing use. This product may also cause increased salivation.

Allergic reactions (including symptoms of anaphylaxis) can occur during the use of the product.

Those who are prone to indigestion may suffer initially from minor degrees of indigestion or heartburn if the 4 mg nicotine gum is used; slower chewing and the use of the 2 mg nicotine gum (if necessary more frequently) will usually overcome this problem.

The chewing gum may stick to and may in rare cases damage dentures.

The adverse reactions observed in patients treated with oral nicotine formulations during clinical trials and post-marketing experience are listed below by system organ class (SOC). Frequencies are defined in accordance with current guidance, as: very common (>1/10); common (>1/100, <1/10); uncommon (>1/1 000, <1/100); rare (>1/10 000, <1/1 000); very rare (<1/10 000), not known - cannot be estimated from the available data.

System Organ Class	**Reported Adverse Event**	**Incidence**
Immune System Disorders	Hypersensitivity[a] Anaphylactic reaction[a]	Common Not known
Psychiatric Disorders	Abnormal dreams[*]	Uncommon
Nervous System Disorders	Headache[a#] Burning sensation[c] Dizziness Dysgeusia Paraesthesia[a] Seizures	Very common Common Common Common Common Not known
Eye Disorders	Blurred vision Lacrimation increased	Not known Not known
Cardiac Disorders	Palpitations[a] Tachycardia[a] Atrial fibrillation	Uncommon Uncommon Very rare
Vascular Disorders	Flushing[a] Hypertension[a]	Uncommon Uncommon

Respiratory, Thoracic and Mediastinal Disorders	Cough** Sore mouth or throat Throat irritation** Bronchospasm Dysphonia Dyspnoea[a] Nasal congestion Sneezing Throat tightness	Common Very common Very common Uncommon Uncommon Uncommon Uncommon Uncommon Uncommon
Gastrointestinal Disorders	Nausea[a] Hiccups**** Abdominal pain Diarrhoea*** Dry mouth Flatulence	Very common Very common Common Common Common Common
	Salivary hypersecretion Stomatitis Vomiting[a] Dyspepsia Eructation Glossitis Oral mucosal blistering and exfoliation Paraesthesia oral*** Dysphagia Hypoaesthesia oral*** Retching Dry throat Gastrointestinal discomfort[a] Lip pain	Common Common Common Common Uncommon Uncommon Uncommon Uncommon Rare Rare Rare Not known Not known Not known
Skin and Subcutaneous Tissue Disorders	Urticaria[a] Hyperhidrosis[a] Pruritus[a] Rash[a] Erythema[a]	Uncommon Uncommon Uncommon Uncommon Not known
Musculoskeletal and Connective Tissue Disorders	Pain in jaw[b] Muscle tightness[b]	Uncommon Not known
General Disorders and Administration Site Conditions	Fatigue[a] Asthenia[a] Chest discomfort and pain[a] Malaise[a] Allergic reactions including angioedema	Common Uncommon Uncommon Uncommon Rare

[a] Systemic effects; [b] Tightness of jaw and pain in jaw with nicotine gum formulation
[c] At the application site
*Identified only for formulations applied during the night
**Higher frequency observed in clinical studies with inhaler formulation.
***Reported the same or less frequently than placebo

**** Higher frequency observed in clinical studies with mouth spray formulation
[#] Although the frequency in the active group is less than that of the placebo group, the frequency in the specific formulation in which the PT was identified as a systemic ADR was greater in the active group than the placebo group.

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

4.9 Overdose

Symptoms: Symptoms of overdose with nicotine from this product may occur in smokers/vapers who have previously had a low nicotine intake from cigarettes/e-cigarettes or if other sources of nicotine are used concomitantly with this product.

Acute or chronic toxicity of nicotine in man is highly dependent on mode and route of administration. Adaptation to nicotine (e.g. in smokers/vapers) is known to significantly increase tolerability compared with non-smokers/vapers. The minimum lethal dose of nicotine in a non-tolerant man has been estimated to be 40 to 60 mg. Symptoms of acute nicotine poisoning include nausea, vomiting, increased salivation, abdominal pain, diarrhoea, sweating, headache, dizziness, disturbed hearing and marked weakness. In extreme cases, these symptoms may be followed by hypotension, rapid or weak or irregular pulse, breathing difficulties, prostration, circulatory collapse and terminal convulsions.

Management of an overdose: All nicotine intake should stop immediately and the patient should be treated symptomatically. Artificial respiration should be instituted if necessary. Activated charcoal reduces the gastro-intestinal absorption of nicotine.

The risk of poisoning as a result of swallowing the gum is very small, as absorption in the absence of chewing is slow and incomplete.

Doses of nicotine that are tolerated by adult smokers/vapers during treatment may produce severe symptoms of poisoning in children and may prove fatal. Suspected nicotine poisoning in a child should be considered a medical emergency and treated immediately.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Drugs used in nicotine dependence
ATC code: N07B A01

The pharmacological effects of nicotine as well documented. Those resulting from chewing Nicorette 4 mg Gum are comparatively small. The response at any one time represents a summation of stimulant and depressant actions from direct, reflex and chemical mediator influences on several organs. The main pharmacological actions are central stimulation and/or depression; transient hyperpnoea; peripheral vasoconstriction (usually associated with a rise in systolic pressure); suppression of appetite and stimulation of peristalsis.

Increased appetite is a recognised symptom of nicotine withdrawal and post-cessation weight gain is common. Clinical trials have demonstrated that Nicotine Replacement Therapy can help control weight following a quit attempt.

5.2 Pharmacokinetic properties

Nicotine administered in chewing gums is readily absorbed from the buccal mucous membranes. Demonstrable blood levels are obtained within 5 – 7 minutes and reach a maximum about 30 minutes after the start of chewing.

Blood levels are roughly proportional to the amount of nicotine chewed and have been shown never to exceed those obtained from smoking cigarettes.

5.3 Preclinical safety data

Preclinical data indicate that nicotine is neither mutagenic nor genotoxic. There are no other findings derived from preclinical testing of relevance to the prescriber in determining the safety of the product which have not been considered in other relevant sections of this Summary of Product Characteristics.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Polacrilin
Chewing gum base, containing butylated hydroxy toluene (E321)
Sorbitol powder
Sorbitol 70%
Flavour for smoker (contains ethanol)
Haverstroo flavour
Sodium carbonate anhydrous
Quinoline Yellow
Glycerol 85%
Talc

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

30 months

6.4 Special precautions for storage
Do not store above 25°C

6.5 Nature and contents of container
PVC/PVDC/Al Blister packed strips each containing 15 pieces supplied in packs of 15, 30, 75, 105, 165 and 210.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal and handling
Dispose of Nicorette Gum sensibly.

Any unused product or waste material should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER
McNeil Products Limited
1 Station Hill Square
Station Hill
Reading
RG1 1LN
UK

8 MARKETING AUTHORISATION NUMBER(S)
PL 15513/0170

9 DATE OF FIRST AUTHRISATION/RENEWAL OF THE AUTHORISATION
24/01/2008

10 DATE OF REVISION OF THE TEXT
29 September 2026

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Nicorette Icy White 2 mg Gum
Boots NicAssist Ice Mint 2 mg Gum.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Chewing Gum containing 2 mg nicotine, as nicotine resinate.

For excipients, see 6.1.

3 PHARMACEUTICAL FORM

Medicated Chewing Gum

A square, coated, white coloured piece of gum

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Nicorette Icy White 2 mg Gum relieves and/or prevents craving and nicotine withdrawal symptoms in nicotine dependence such as those arising from the use of tobacco or electronic cigarettes. It is indicated to aid quitting or reduction prior to quitting, to assist those who are unwilling or unable to use such products, and as a safer alternative to smoking tobacco for smokers and those around them.

Nicorette Icy White 2 mg Gum is indicated in pregnant and lactating women making a quit attempt.

4.2 Posology and method of administration

Adults and children over 12 years of age
Nicorette Icy White 2 mg Gum should be chewed slowly according to the instructions.

The strength of gum to be used will depend on the smoking/vaping habits of the individual. In general, if the patient smokes 20 or less cigarettes a day, 2 mg nicotine gum is indicated. If more than 20 cigarettes per day are smoked, 4 mg nicotine gum will be needed to meet the withdrawal of the high serum nicotine levels from heavy smoking.

Light to moderate vapers (e.g. vape infrequently or use low strength e-liquid) should start with 2 mg nicotine gum. If the 2 mg nicotine gum does not relieve

the urge to vape, 4 mg nicotine gum should be used. Heavy vapers (e.g. vape frequently or use high strength e-liquid) should use 4 mg nicotine gum.

Nicorette Icy White 2 mg Gum should be used whenever the urge to smoke or vape is felt or to prevent cravings in situations where these are likely to occur.

Patients willing or able to stop smoking/vaping immediately should initially replace all their cigarettes/e-cigarettes with the gum and as soon as they are able, reduce the number of gums used until they have stopped completely.

Patients aiming to reduce cigarettes/e-cigarettes should use Nicorette Icy White 2 mg Gum between smoking/vaping episodes, as needed, to prolong smoke/vape-free intervals and to reduce their use as much as possible.

As soon as they are ready patients should aim to quit smoking/vaping completely.

Maximum daily dose: 15 pieces per day.

When making a quit attempt behavioural therapy, advice and support will normally improve the success rate. Those who have quit smoking/vaping but are having difficulty discontinuing Nicorette Icy White 2 mg Gum are recommended to contact their pharmacist or doctor for advice.

For those using the 4 mg gum, switching to the 2 mg gum may be helpful when stopping treatment or reducing the number of gums used each day.

The chewing gums should be used whenever there is an urge to smoke/vape according to the "chew and rest" technique described on the pack. After about 30 minutes of such use, the gum will be exhausted. Absorption of nicotine is through the buccal mucosa, any nicotine, which is swallowed being destroyed by the liver.

4.3 Contraindications

Hypersensitivity to nicotine or any component of the chewing gum.

Nicorette Icy White 2 mg Gum is contraindicated in children under the age of 12 years.

4.4 Special warnings and precautions for use

Any risks that may be associated with NRT are substantially outweighed by the well-established dangers of continued smoking. The risks of continued vaping are not yet established.

A risk-benefit assessment should be made by an appropriate healthcare professional for patients with the following conditions:

Underlying cardiovascular disease: In stable cardiovascular disease this product presents a lesser hazard than continuing to smoke. However

dependent smokers currently hospitalised as a result of myocardial infarction, unstable or worsening angina including Prinzmetal angina, severe dysrhythmia or CVA and who are considered to be haemodynamically unstable and/or who suffer with uncontrolled hypertension should be encouraged to stop smoking with non-pharmacological interventions. If this fails, this product may be considered, but as data on safety in this patient group are limited, initiation should only be under medical supervision. The risks of continued vaping are not yet established.

Diabetes mellitus: Patients with diabetes mellitus should be advised to monitor their blood sugar levels more closely than usual when quitting and NRT is initiated as reductions in nicotine induced catecholamine release can affect carbohydrate metabolism.

GI disease: Nicotine may exacerbate symptoms in patients suffering from oesophagitis, gastritis or peptic ulcers and NRT preparations should be used with caution in these conditions. Ulcerative stomatitis has been reported.

Renal or hepatic impairment: This product should be used with caution in patients with moderate to severe hepatic impairment and/or severe renal impairment as the clearance of nicotine or its metabolites may be decreased with the potential for increased adverse effects.

Seizures: Potential risks and benefits of nicotine should be carefully evaluated before use in subjects with a history of epilepsy as cases of convulsions have been reported in association with nicotine.

Danger in children: Doses of nicotine tolerated by adult and adolescent smokers or vapers can produce severe toxicity in children that may be fatal. Products containing nicotine should not be left where they may be misused, handled or ingested by children. Nicotine gum should be disposed of with care.

Phaeochromocytoma and uncontrolled hyperthyroidism: As nicotine causes release of catecholamines, this product should be used with caution in patients with uncontrolled hyperthyroidism or phaeochromocytoma.

Transferred dependence: Transferred dependence is rare and is both less harmful and easier to break than smoking dependence.

Stopping smoking: Polycyclic aromatic hydrocarbons in tobacco smoke induce the metabolism of drugs metabolised by CYP 1A2 (and possibly by CYP 1A1). When a smoker stops smoking, this may result in slower metabolism and a consequent rise in blood levels of such drugs. This is of potential clinical importance for products with a narrow therapeutic window, e.g. theophylline, clozapine and ropinirole.

Excipients: This product also contains butylated hydroxy toluene (E321); this may cause irritation to the mucous membranes.

Denture warning: Patients who wear dentures may experience difficulty in chewing this product. The chewing gum may stick to and may in rare cases damage dentures.

4.5 Interaction with other medicinal products and other forms of interaction

No clinically relevant interactions between nicotine replacement therapy and other drugs have definitely been established. However nicotine may possibly enhance the haemodynamic effects of adenosine i.e. increase in blood pressure and heart rate and also increase pain response (angina-pectoris type chest pain) provoked by adenosine administration.

4.6 Fertility, pregnancy and lactation

Pregnancy

Stopping smoking is the single most effective intervention for improving the health of both the pregnant smoker and her baby, and the earlier abstinence is achieved the better. Ideally smoking cessation during pregnancy should be achieved without NRT. Nicotine passes to the foetus and affects its breathing movements and circulation. The effect on the circulation is dose-dependent. However, if the mother cannot (or is considered unlikely to) quit without pharmacological support, NRT may be used as the risk to the foetus is lower than that expected with smoking tobacco. Stopping completely is by far the best option but if this is not achievable this product may be used in pregnancy as a safer alternative to smoking. Because of the potential for nicotine-free periods, intermittent dose forms are preferable, but patches may be considered as an alternative if there is significant nausea and/or vomiting. If patches are used they should, if possible, be removed at night when the foetus would not normally be exposed to nicotine.

There is no or limited data regarding the effect of vaping in pregnancy fertility.

Use of NRT by the pregnant smoker/vaper should only be initiated after advice from a health care professional.

Lactation

Nicotine should be avoided during breast-feeding. The relatively small amounts of nicotine found in breast milk during NRT use are less hazardous to the infant than second-hand smoke. Intermittent dose forms would minimize the amount of nicotine in breast milk and permit feeding when levels were at their lowest.

There is no or limited data regarding the effect of vaping in lactating women.

Use of NRT by breast feeding smokers/vapers should only be initiated after advice from a health care professional. Women should use the product as soon as possible after breastfeeding.

Fertility
In females tobacco smoking delays time to conception, decreases in-vitro fertilization success rates, and significantly increases the risk of infertility.

In males tobacco smoking reduces sperm production, increases oxidative stress, and DNA damage. Spermatozoa from smokers have reduced fertilizing capacity.

The specific contribution of nicotine to these effects in humans is unknown.

There is no or limited data regarding the effect of vaping on fertility.

4.7 Effects on ability to drive and use machines

This product has no or negligible influence on the ability to drive and use machines**.**

4.8 Undesirable effects

Effects of Smoking Cessation

Some symptoms may be related to nicotine withdrawal associated with stopping smoking. These can include irritability/aggression, dysphoria/depressed mood, anxiety, restlessness, poor concentration, increased appetite/weight gain, urges to smoke (cravings), night-time awakenings/sleep disturbance, decreased heart rate, dizziness, presyncopal symptoms, cough, constipation, gingival bleeding or nasopharyngitis.

Increased frequency of aphthous ulcer may occur after abstinence from smoking. The causality is unclear.

Effects of Vaping Cessation

The nicotine withdrawal effects of vaping cessation have not been established; however it is anticipated that many of the effects relating to nicotine withdrawal will be the same as those seen with tobacco smoking cessation.

Adverse Drug Reactions

This product may cause adverse reactions similar to those associated with nicotine given by other means, including smoking and vaping, and these are mainly dose-dependent. At recommended doses this product has not been found to cause any serious adverse effects. Most of the undesirable effects reported by the patients occur during the first 3-4 weeks after start of treatment.

Excessive consumption of this product by those who have not been in the habit of inhaling tobacco smoke or vaping could possibly lead to nausea, faintness or headaches. Excessive swallowing of dissolved nicotine may, at first, cause hiccupping.

Nicotine from the gum may sometimes cause a slight irritation of the throat at the start of treatment, however most subjects adapt to this with ongoing use. This product may also cause increased salivation.

Allergic reactions (including symptoms of anaphylaxis) can occur during the use of the product.

Those who are prone to indigestion may suffer initially from minor degrees of indigestion or heartburn if the 4 mg nicotine gum is used; slower chewing and the use of the 2 mg nicotine gum (if necessary more frequently) will usually overcome this problem.

The chewing gum may stick to and may in rare cases damage dentures.

The adverse reactions observed in patients treated with oral nicotine formulations during clinical trials and post-marketing experience are listed below by system organ class (SOC). Frequencies are defined in accordance with current guidance, as: very common (>1/10); common (>1/100, <1/10); uncommon (>1/1 000, <1/100); rare (>1/10 000, <1/1 000); very rare (<1/10 000), not known - cannot be estimated from the available data.

System Organ Class	**Reported Adverse Event**	**Incidence**
Immune System Disorders	Hypersensitivity[a] Anaphylactic reaction[a]	Common Not known
Psychiatric Disorders	Abnormal dreams[*]	Uncommon
Nervous System Disorders	Headache[a#] Burning sensation[c] Dizziness Dysgeusia Paraesthesia[a] Seizures	Very common Common Common Common Common Not known
Eye Disorders	Blurred vision Lacrimation increased	Not known Not known
Cardiac Disorders	Palpitations[a] Tachycardia[a] Atrial fibrillation	Uncommon Uncommon Very rare
Vascular Disorders	Flushing[a] Hypertension[a]	Uncommon Uncommon
Respiratory, Thoracic and Mediastinal Disorders	Cough** Sore mouth or throat Throat irritation** Bronchospasm Dysphonia Dyspnoea[a] Nasal congestion Sneezing Throat tightness	Common Very common Very common Uncommon Uncommon Uncommon Uncommon Uncommon Uncommon
Gastrointestinal Disorders	Nausea[a] Hiccups**** Abdominal pain	Very common Very common Common

	Diarrhoea[***] Dry mouth Flatulence Salivary hypersecretion Stomatitis Vomiting[a] Dyspepsia Eructation Glossitis Oral mucosal blistering and exfoliation Paraesthesia oral[***] Dysphagia Hypoaesthesia oral[***] Retching Dry throat Gastrointestinal discomfort[a] Lip pain	Common Common Common Common Common Common Common Uncommon Uncommon Uncommon Uncommon Rare Rare Rare Not known Not known Not known
Skin and Subcutaneous Tissue Disorders	Urticaria[a] Hyperhidrosis[a] Pruritus[a] Rash[a] Erythema[a]	Uncommon Uncommon Uncommon Uncommon Not known
Musculoskeletal and Connective Tissue Disorders	Pain in jaw[b] Muscle tightness[b]	Uncommon Not known
General Disorders and Administration Site Conditions	Fatigue[a] Asthenia[a] Chest discomfort and pain[a] Malaise[a] Allergic reactions including angioedema	Common Uncommon Uncommon Uncommon Rare

[a] Systemic effects; [b] Tightness of jaw and pain in jaw with nicotine gum formulation
[c] At the application site
[*]Identified only for formulations applied during the night
[**]Higher frequency observed in clinical studies with inhaler formulation.
***Reported the same or less frequently than placebo
**** Higher frequency observed in clinical studies with mouth spray formulation
[#] Although the frequency in the active group is less than that of the placebo group, the frequency in the specific formulation in which the PT was identified as a systemic ADR was greater in the active group than the placebo group.

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

4.9 Overdose

Symptoms: Symptoms of overdose with nicotine from this product may occur in smokers/vapers who have previously had a low nicotine intake from cigarettes/e-cigarettes or if other sources of nicotine are used concomitantly with this product.

Acute or chronic toxicity of nicotine in man is highly dependent on mode and route of administration. Adaptation to nicotine (e.g. in smokers/vapers) is known to significantly increase tolerability compared with non-smokers/vapers. The minimum lethal dose of nicotine in a non-tolerant man has been estimated to be 40 to 60 mg. Symptoms of acute nicotine poisoning include nausea, vomiting, increased salivation, abdominal pain, diarrhoea, sweating, headache, dizziness, disturbed hearing and marked weakness. In extreme cases, these symptoms may be followed by hypotension, rapid or weak or irregular pulse, breathing difficulties, prostration, circulatory collapse and terminal convulsions.

Management of an overdose: All nicotine intake should stop immediately and the patient should be treated symptomatically. Artificial respiration should be instituted if necessary. Activated charcoal reduces the gastro-intestinal absorption of nicotine.

The risk of poisoning as a result of swallowing the gum is very small, as absorption in the absence of chewing is slow and incomplete.

Doses of nicotine that are tolerated by adult smokers/vapers during treatment may produce severe symptoms of poisoning in children and may prove fatal. Suspected nicotine poisoning in a child should be considered a medical emergency and treated immediately.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Drugs used in nicotine dependence
ATC code: N07B A01

The pharmacological effects of nicotine are well documented. Those resulting from chewing Nicorette 2 mg Gum are comparatively small. The response at any one time represents a summation of stimulant and depressant actions from direct, reflex and chemical mediator influences on several organs. The main pharmacological actions are central stimulation and/or depression; transient hyperpnoea; peripheral vasoconstriction (usually associated with a rise in systolic pressure); suppression of appetite and stimulation of peristalsis.

The gum contains a number of ingredients that are recognized as having properties for removal of dental staining. Clinical studies have shown that the gum helps to improve tooth whiteness.

Increased appetite is a recognised symptom of nicotine withdrawal and post-cessation weight gain is common. Clinical trials have demonstrated that Nicotine Replacement Therapy can help control weight following a quit attempt.

5.2 Pharmacokinetic properties

Nicotine administered in chewing gums is readily absorbed from the buccal mucous membranes. Demonstrable blood levels are obtained within 5 – 7 minutes and reach a maximum about 30 minutes after the start of chewing. Blood levels are roughly proportional to the amount of nicotine chewed and have been shown never to exceed those obtained from smoking cigarettes.

5.3 Preclinical safety data

Preclinical data indicate that nicotine is neither mutagenic nor genotoxic. There are no other findings derived from preclinical testing of relevance to the prescriber in determining the safety of the product, which have not been considered in other relevant sections of this Summary of Product Characteristics.

5 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Core Gum
Chewing gum base, containing butylated hydroxy toluene (E321)
Xylitol
Peppermint oil
Sodium carbonate, anhydrous
Sodium hydrogen carbonate
Acesulfame Potassium
Levomenthol
Magnesium oxide, light
Talc

Sub Coating
Winterfresh
Hypromellose
Sucralose
Polysorbate 80
Purified water

Hard Coating
Xylitol
Starch
Titanium dioxide (E171)
Winterfresh
Carnauba wax
Purified water

6.2 Incompatibilities
Not applicable.

6.3 Shelf life
Blister: 3 years
Box: 2 years. Shelf life after opening 3 months.

6.4 Special precautions for storage
Do not store above 25°C.

6.5 Nature and contents of container
PVC/PVDC/Al Blister packed strips each containing 6,10 or 15 pieces supplied in packs of 10, 12, 15, 30, 75, 105, 165 and 210 pieces.

and

Laminated cardboard box, wrapped in a transparent plastic film, containing 25 pieces, supplied in packs of 25, 100 and 200.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal
Dispose of Nicorette Gum sensibly.

Any unused product or waste material should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER
McNeil Products Limited
1 Station Hill Square
Station Hill
Reading
RG1 1LN
UK

8 MARKETING AUTHORISATION NUMBER
PL 15513/0152

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION
28 August 2025

10 DATE OF REVISION OF THE TEXT

04 Jun 2026

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Nicorette Icy White 4 mg Gum
Boots NicAssist Ice Mint 4 mg Gum

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Chewing Gum containing 4 mg nicotine, as nicotine resinate.

For excipients, see 6.1.

3 PHARMACEUTICAL FORM

Medicated Chewing Gum

A square, coated, crème coloured piece of gum.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Nicorette Icy White 4 mg Gum relieves and/or prevents craving and nicotine withdrawal symptoms in nicotine dependence such as those arising from the use of tobacco or electronic cigarettes. It is indicated to aid quitting or reduction prior to quitting, to assist those who are unwilling or unable to use such products, and as a safer alternative to smoking for smokers and those around them.

Nicorette Icy White 4 mg Gum is indicated in pregnant and lactating women making a quit attempt.

4.2 Posology and method of administration

Adults and children over 12 years of age
Nicorette Icy White 4 mg Gum should be chewed slowly according to the instructions.

The strength of gum to be used will depend on the smoking/vaping habits of the individual. In general, if the patient smokes 20 or less cigarettes a day, 2 mg nicotine gum is indicated. If more than 20 cigarettes per day are smoked, 4 mg nicotine gum will be needed to meet the withdrawal of the high serum nicotine levels from heavy smoking.

Light to moderate vapers (e.g. vape infrequently or use low strength e-liquid) should start with 2 mg nicotine gum. If the 2 mg nicotine gum does not relieve the urge to vape, 4 mg nicotine gum should be used. Heavy vapers (e.g. vape frequently or use high strength e-liquid) should use 4 mg nicotine gum.

Nicorette Icy White 4 mg Gum should be used whenever the urge to smoke or vape is felt or to prevent cravings in situations where these are likely to occur.

Patients willing or able to stop smoking/vaping immediately should initially replace all their cigarettes/e-cigarettes with the gum and as soon as they are able, reduce the number of gums used until they have stopped completely.

Patients aiming to reduce cigarettes/e-cigarettes should use Nicorette Icy White 4 mg Gum between smoking/vaping episodes, as needed, to prolong smoke/vape-free intervals and to reduce their use as much as possible.

As soon as they are ready patients should aim to quit smoking/vaping completely.

Maximum daily dose: 15 pieces per day.

When making a quit attempt behavioural therapy, advice and support will normally improve the success rate. Those who have quit smoking/vaping but are having difficulty discontinuing Nicorette Icy White 4 mg Gum are recommended to contact their pharmacist or doctor for advice.

For those using the 4 mg gum, switching to the 2 mg gum may be helpful when stopping treatment or reducing the number of gums used each day.

The chewing gums should be used whenever there is an urge to smoke/vape according to the "chew and rest" technique described on the pack. After about 30 minutes of such use, the gum will be exhausted. Absorption of nicotine is through the buccal mucosa, any nicotine, which is swallowed being destroyed by the liver.

4.3 Contraindications

Hypersensitivity to nicotine or any component of the chewing gum.

Nicorette Icy White 4 mg Gum is contraindicated in children under the age of 12 years.

4.4 Special warnings and precautions for use

Any risks that may be associated with NRT are substantially outweighed by the well-established dangers of continued smoking. The risks of continued vaping are not yet established.

A risk-benefit assessment should be made by an appropriate healthcare professional for patients with the following conditions:

Underlying cardiovascular disease: In stable cardiovascular disease this product presents a lesser hazard than continuing to smoke. However dependent smokers currently hospitalised as a result of myocardial infarction, unstable or worsening angina including Prinzmetal angina, severe

dysrhythmia or CVA and who are considered to be haemodynamically unstable and/or who suffer with uncontrolled hypertension should be encouraged to stop smoking with non-pharmacological interventions. If this fails, this product may be considered, but as data on safety in this patient group are limited, initiation should only be under medical supervision. The risks of continued vaping are not yet established.

Diabetes mellitus: Patients with diabetes mellitus should be advised to monitor their blood sugar levels more closely than usual when quitting and NRT is initiated as reductions in nicotine induced catecholamine release can affect carbohydrate metabolism.

GI disease: Nicotine may exacerbate symptoms in patients suffering from oesophagitis, gastritis or peptic ulcers and NRT preparations should be used with caution in these conditions. Ulcerative stomatitis has been reported.

Renal or hepatic impairment: This product should be used with caution in patients with moderate to severe hepatic impairment and/or severe renal impairment as the clearance of nicotine or its metabolites may be decreased with the potential for increased adverse effects.

Seizures: Potential risks and benefits of nicotine should be carefully evaluated before use in subjects with a history of epilepsy as cases of convulsions have been reported in association with nicotine.

Danger in children: Doses of nicotine tolerated by adult and adolescent smokers or vapers can produce severe toxicity in children that may be fatal. Products containing nicotine should not be left where they may be misused, handled or ingested by children. Nicotine gum should be disposed of with care.

Phaeochromocytoma and uncontrolled hyperthyroidism: As nicotine causes release of catecholamines, this product should be used with caution in patients with uncontrolled hyperthyroidism or phaeochromocytoma.

Transferred dependence: Transferred dependence is rare and is both less harmful and easier to break than smoking dependence.

Stopping smoking: Polycyclic aromatic hydrocarbons in tobacco smoke induce the metabolism of drugs metabolised by CYP 1A2 (and possibly by CYP 1A1). When a smoker stops smoking, this may result in slower metabolism and a consequent rise in blood levels of such drugs. This is of potential clinical importance for products with a narrow therapeutic window, e.g. theophylline, clozapine and ropinirole.

Excipients: This product also contains butylated hydroxyl toluene (E321); this may cause irritation to the mucous membranes.

Denture warning: Patients who wear dentures may experience difficulty in chewing this product. The chewing gum may stick to and may in rare cases damage dentures.

4.5 Interaction with other medicinal products and other forms of interaction

No clinically relevant interactions between nicotine replacement therapy and other drugs have definitely been established. However nicotine may possibly enhance the haemodynamic effects of adenosine i.e. increase in blood pressure and heart rate and also increase pain response (angina-pectoris type chest pain) provoked by adenosine administration.

4.6 Fertility, pregnancy and lactation

Pregnancy

Stopping smoking is the single most effective intervention for improving the health of both the pregnant smoker and her baby, and the earlier abstinence is achieved the better. Ideally smoking cessation during pregnancy should be achieved without NRT. Nicotine passes to the foetus and affects its breathing movements and circulation. The effect on the circulation is dose-dependent. However, if the mother cannot (or is considered unlikely to) quit without pharmacological support, NRT may be used as the risk to the foetus is lower than that expected with smoking tobacco. Stopping completely is by far the best option but if this is not achievable this product may be used in pregnancy as a safer alternative to smoking. Because of the potential for nicotine-free periods, intermittent dose forms are preferable, but patches may be considered as an alternative if there is significant nausea and/or vomiting. If patches are used they should, if possible, be removed at night when the foetus would not normally be exposed to nicotine.

There is no or limited data regarding the effect of vaping in pregnancy.

Use of NRT by the pregnant smoker/vaper should only be initiated after advice from a health care professional.

Lactation

Nicotine should be avoided during breast-feeding. The relatively small amounts of nicotine found in breast milk during NRT use are less hazardous to the infant than second-hand smoke. Intermittent dose forms would minimize the amount of nicotine in breast milk and permit feeding when levels were at their lowest.

There is no or limited data regarding the effect of vaping in lactating women.

Use of NRT by breast feeding smokers/vapers should only be initiated after advice from a health care professional. Women should use the product as soon as possible after breastfeeding.

Fertility

In females tobacco smoking delays time to conception, decreases in-vitro fertilization success rates, and significantly increases the risk of infertility.

In males tobacco smoking reduces sperm production, increases oxidative stress, and DNA damage. Spermatozoa from smokers have reduced fertilizing capacity.

The specific contribution of nicotine to these effects in humans is unknown.

There is no or limited data regarding the effect of vaping on fertility.

4.7 Effects on ability to drive and use machines

This product has no or negligible influence on the ability to drive and use machines.

4.8 Undesirable effects

Effects of Smoking Cessation

Some symptoms may be related to nicotine withdrawal associated with stopping smoking. These can include irritability/aggression, dysphoria/depressed mood, anxiety, restlessness, poor concentration, increased appetite/weight gain, urges to smoke (cravings), night-time awakenings/sleep disturbance, decreased heart rate, dizziness, presyncopal symptoms, cough, constipation, gingival bleeding or nasopharyngitis.

Increased frequency of aphthous ulcer may occur after abstinence from smoking. The causality is unclear.

Effects of Vaping Cessation

The nicotine withdrawal effects of vaping cessation have not been established; however it is anticipated that many of the effects relating to nicotine withdrawal will be the same as those seen with tobacco smoking cessation.

Adverse Drug Reactions

This product may cause adverse reactions similar to those associated with nicotine given by other means, including smoking and vaping, and these are mainly dose-dependent. At recommended doses this product has not been found to cause any serious adverse effects. Most of the undesirable effects reported by the patients occur during the first 3-4 weeks after start of treatment.

Excessive consumption of this product by those who have not been in the habit of inhaling tobacco smoke or vaping could possibly lead to nausea, faintness or headaches. Excessive swallowing of dissolved nicotine may, at first, cause hiccupping.

Nicotine from the gum may sometimes cause a slight irritation of the throat at the start of treatment, however most subjects adapt to this with ongoing use. This product may also cause increased salivation.

Allergic reactions (including symptoms of anaphylaxis) can occur during the use of the product.

Those who are prone to indigestion may suffer initially from minor degrees of indigestion or heartburn if the 4 mg nicotine gum is used; slower chewing and the use of the 2 mg nicotine gum (if necessary more frequently) will usually overcome this problem.

The chewing gum may stick to and may in rare cases damage dentures.

The adverse reactions observed in patients treated with oral nicotine formulations during clinical trials and post-marketing experience are listed below by system organ class (SOC). Frequencies are defined in accordance with current guidance, as: very common (>1/10); common (>1/100, <1/10); uncommon (>1/1 000, <1/100); rare (>1/10 000, <1/1 000); very rare (<1/10 000), not known - cannot be estimated from the available data.

System Organ Class	**Reported Adverse Event**	**Incidence**
Immune System Disorders	Hypersensitivity[a] Anaphylactic reaction[a]	Common Not known
Psychiatric Disorders	Abnormal dreams[*]	Uncommon
Nervous System Disorders	Headache[a#] Burning sensation[c] Dizziness Dysgeusia Paraesthesia[a] Seizures	Very common Common Common Common Common Not known
Eye Disorders	Blurred vision Lacrimation increased	Not known Not known
Cardiac Disorders	Palpitations[a] Tachycardia[a] Atrial fibrillation	Uncommon Uncommon Very rare
Vascular Disorders	Flushing[a] Hypertension[a]	Uncommon Uncommon
Respiratory, Thoracic and Mediastinal Disorders	Cough** Sore mouth or throat Throat irritation** Bronchospasm Dysphonia Dyspnoea[a] Nasal congestion Sneezing Throat tightness	Common Very common Very common Uncommon Uncommon Uncommon Uncommon Uncommon Uncommon
Gastrointestinal Disorders	Nausea[a] Hiccups**** Abdominal pain Diarrhoea[***] Dry mouth Flatulence	Very common Very common Common Common Common Common

	Salivary hypersecretion Stomatitis Vomiting[a] Dyspepsia Eructation Glossitis Oral mucosal blistering and exfoliation Paraesthesia oral[***] Dysphagia Hypoaesthesia oral[***] Retching Dry throat Gastrointestinal discomfort[a] Lip pain	Common Common Common Common Uncommon Uncommon Uncommon Uncommon Rare Rare Rare Not known Not known Not known
Skin and Subcutaneous Tissue Disorders	Urticaria[a] Hyperhidrosis[a] Pruritus[a] Rash[a] Erythema[a]	Uncommon Uncommon Uncommon Uncommon Not known
Musculoskeletal and Connective Tissue Disorders	Pain in jaw[b] Muscle tightness[b]	Uncommon Not known
General Disorders and Administration Site Conditions	Fatigue[a] Asthenia[a] Chest discomfort and pain[a] Malaise[a] Allergic reactions including angioedema	Common Uncommon Uncommon Uncommon Rare

[a] Systemic effects; [b] Tightness of jaw and pain in jaw with nicotine gum formulation
[c] At the application site
[*]Identified only for formulations applied during the night
[**]Higher frequency observed in clinical studies with inhaler formulation.
***Reported the same or less frequently than placebo
**** Higher frequency observed in clinical studies with mouth spray formulation
[#] Although the frequency in the active group is less than that of the placebo group, the frequency in the specific formulation in which the PT was identified as a systemic ADR was greater in the active group than the placebo group.

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

4.9 Overdose

Symptoms: Symptoms of overdose with nicotine from this product may occur in smokers/vapers who have previously had a low nicotine intake from cigarettes/e-cigarettes or if other sources of nicotine are used concomitantly with this product.

Acute or chronic toxicity of nicotine in man is highly dependent on mode and route of administration. Adaptation to nicotine (e.g. in smokers/vapers) is known to significantly increase tolerability compared with non-smokers/vapers. The minimum lethal dose of nicotine in a non-tolerant man has been estimated to be 40 to 60 mg. Symptoms of acute nicotine poisoning include nausea, vomiting, increased salivation, abdominal pain, diarrhoea, sweating, headache, dizziness, disturbed hearing and marked weakness. In extreme cases, these symptoms may be followed by hypotension, rapid or weak or irregular pulse, breathing difficulties, prostration, circulatory collapse and terminal convulsions.

Management of an overdose: All nicotine intake should stop immediately and the patient should be treated symptomatically. Artificial respiration should be instituted if necessary. Activated charcoal reduces the gastro-intestinal absorption of nicotine.

The risk of poisoning as a result of swallowing the gum is very small, as absorption in the absence of chewing is slow and incomplete.

Doses of nicotine that are tolerated by adult smokers/vapers during treatment may produce severe symptoms of poisoning in children and may prove fatal. Suspected nicotine poisoning in a child should be considered a medical emergency and treated immediately.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Drugs used in nicotine dependence
ATC code: N07B A01

The pharmacological effects of nicotine are well documented. Those resulting from chewing Nicorette 4 mg Gum are comparatively small. The response at any one time represents a summation of stimulant and depressant actions from direct, reflex and chemical mediator influences on several organs. The main pharmacological actions are central stimulation and/or depression; transient hyperpnoea; peripheral vasoconstriction (usually associated with a rise in systolic pressure); suppression of appetite and stimulation of peristalsis.

The gum contains a number of ingredients that are recognized as having properties for removal of dental staining. Clinical studies have shown that the gum helps to improve tooth whiteness.

Increased appetite is a recognised symptom of nicotine withdrawal and post-cessation weight gain is common. Clinical trials have demonstrated that Nicotine Replacement Therapy can help control weight following a quit attempt.

5.2 Pharmacokinetic properties

Nicotine administered in chewing gums is readily absorbed from the buccal mucous membranes. Demonstrable blood levels are obtained within 5 – 7 minutes and reach a maximum about 30 minutes after the start of chewing. Blood levels are roughly proportional to the amount of nicotine chewed and have been shown never to exceed those obtained from smoking cigarettes.

5.3 Preclinical safety data

Preclinical data indicate that nicotine is neither mutagenic nor genotoxic. There are no other findings derived from preclinical testing of relevance to the prescriber in determining the safety of the product, which have not been considered in other relevant sections of this Summary of Product Characteristics.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Core gum
Chewing gum base, containing butylated hydroxyl toluene (E321)
Xylitol
Peppermint oil
Sodium carbonate, anhydrous
Sodium hydrogen carbonate
Acesulfame Potassium
Levomenthol
Magnesium oxide, light
Quinoline yellow Al lake (E104)
Talc

Sub coating
Winterfresh
Hypromellose
Sucralose
Polysorbate 80

Hard coating
Xylitol
Starch
Titanium dioxide (E171)
Winterfresh
Quinoline yellow Al lake (E104)
Carnauba wax

6.2 Incompatibilities
Not applicable

6.3 Shelf life
Blister: 3 years
Box: 3 years. Shelf life after opening 3 months.

6.4 Special precautions for storage
Do not store above 25°C.

6.5 Nature and contents of container
PVC/PVDC/Al Blister packed strips each containing 6, 10 or 15 pieces supplied in packs of 10, 12, 15, 30, 75, 105, 165 and 210 pieces.
and
Laminated cardboard box, wrapped in a transparent plastic film, containing 25 pieces, supplied in packs of 25, 100 and 200.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal
Dispose of Nicorette Gum sensibly.

Any unused product or waste material should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER
McNeil Products Limited
1 Station Hill Square
Station Hill
Reading
RG1 1LN
UK

8 MARKETING AUTHORISATION NUMBER
PL 15513/0153

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

28/08/2025

10 DATE OF REVISION OF THE TEXT
04 Jun 2026

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Nicorette Fruitfusion 2 mg Gum
Boots NicAssist Fruit Fresh 2 mg Gum

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Chewing Gum containing 2 mg nicotine, as nicotine resinate.

Excipients with known effect:
Butylated hydroxytoluene

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Medicated Chewing Gum

A square, coated, whitish piece of gum

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

This product relieves and/or prevents craving and nicotine withdrawal symptoms in nicotine dependence such as those arising from the use of tobacco or electronic cigarettes. It is indicated to aid quitting or reduction prior to quitting, to assist those who are unwilling or unable to use such products, and as a safer alternative to smoking tobacco for smokers and those around them.

This product is indicated in pregnant and lactating women making a quit attempt.

4.2 Posology and method of administration

Adults and children over 12 years of age

This product should be chewed slowly according to the instructions.

The strength of gum to be used will depend on the smoking/vaping habits of the individual. In general, if the patient smokes 20 or less cigarettes a day, 2 mg nicotine gum is indicated. If more than 20 cigarettes per day are smoked, 4 mg nicotine gum will be needed to meet the withdrawal of the high serum nicotine levels from heavy smoking.

Light to moderate vapers (e.g. vape infrequently or use low strength e-liquid) should start with 2 mg nicotine gum. If the 2 mg nicotine gum does not relieve

the urge to vape, 4 mg nicotine gum should be used. Heavy vapers (e.g. vape frequently or use high strength e-liquid) should use 4 mg nicotine gum.

This product should be used whenever the urge to smoke or vape is felt or to prevent cravings in situations where these are likely to occur.

Patients willing or able to stop smoking/vaping immediately should initially replace all their cigarettes/e-cigarettes with the gum and as soon as they are able, reduce the number of gums used until they have stopped completely.

Patients aiming to reduce cigarettes/e-cigarettes should use this product between smoking/vaping episodes, as needed, to prolong smoke/vape-free intervals and to reduce their use as much as possible.

As soon as they are ready patients should aim to quit smoking/vaping completely.

Maximum daily dose: 15 pieces per day.

When making a quit attempt behavioural therapy, advice and support will normally improve the success rate. Those who have quit smoking/vaping but are having difficulty discontinuing this product are recommended to contact their pharmacist or doctor for advice.

For those using the 4 mg gum, switching to the 2 mg gum may be helpful when stopping treatment or reducing the number of gums used each day.

The chewing gums should be used whenever there is an urge to smoke/vape according to the "chew and rest" technique described on the pack. After about 30 minutes of such use, the gum will be exhausted. Absorption of nicotine is through the buccal mucosa, any nicotine which is swallowed being destroyed by the liver.

4.3 Contraindications

Hypersensitivity to nicotine or any component of the chewing gum.

This product is contraindicated in children under the age of 12 years.

4.4 Special warnings and precautions for use

Any risks that may be associated with NRT are substantially outweighed by the well-established dangers of continued smoking. The risks of continued vaping are not yet established.

A risk-benefit assessment should be made by an appropriate healthcare professional for patients with the following conditions:

Underlying cardiovascular disease: In stable cardiovascular disease this product presents a lesser hazard than continuing to smoke. However dependent smokers currently hospitalised as a result of myocardial infarction, unstable or worsening angina including Prinzmetal angina, severe

dysrhythmia or CVA and who are considered to be haemodynamically unstable and/or who suffer with uncontrolled hypertension should be encouraged to stop smoking with non-pharmacological interventions. If this fails, this product may be considered, but as data on safety in this patient group are limited, initiation should only be under medical supervision. The risks of continued vaping are not yet established.

Diabetes mellitus: Patients with diabetes mellitus should be advised to monitor their blood sugar levels more closely than usual when quitting and NRT is initiated as reductions in nicotine induced catecholamine release can affect carbohydrate metabolism.

GI disease: Nicotine may exacerbate symptoms in patients suffering from oesophagitis, gastritis or peptic ulcers and NRT preparations should be used with caution in these conditions. Ulcerative stomatitis has been reported.

Renal or hepatic impairment: This product should be used with caution in patients with moderate to severe hepatic impairment and/or severe renal impairment as the clearance of nicotine or its metabolites may be decreased with the potential for increased adverse effects.

Seizures: Potential risks and benefits of nicotine should be carefully evaluated before use in subjects with a history of epilepsy as cases of convulsions have been reported in association with nicotine.

Danger in children: Doses of nicotine tolerated by adult and adolescent smokers or vapers can produce severe toxicity in children that may be fatal. Products containing nicotine should not be left where they may be misused, handled or ingested by children. Nicotine gum should be disposed of with care.

Phaeochromocytoma and uncontrolled hyperthyroidism: As nicotine causes release of catecholamines, this product should be used with caution in patients with uncontrolled hyperthyroidism or phaeochromocytoma.

Transferred dependence: Transferred dependence is rare and is both less harmful and easier to break than smoking dependence.

Stopping smoking: Polycyclic aromatic hydrocarbons in tobacco smoke induce the metabolism of drugs metabolised by CYP 1A2 (and possibly by CYP 1A1). When a smoker stops smoking, this may result in slower metabolism and a consequent rise in blood levels of such drugs. This is of potential clinical importance for products with a narrow therapeutic window, e.g. theophylline, clozapine and ropinirole.

Excipients: This product also contains butylated hydroxy toluene (E321); this may cause irritation to the mucous membranes.

Denture warning: Patients who wear dentures may experience difficulty in chewing this product. The chewing gum may stick to and may in rare cases damage dentures.

4.5 Interaction with other medicinal products and other forms of interaction

No clinically relevant interactions between nicotine replacement therapy and other drugs have definitely been established. However nicotine may possibly enhance the haemodynamic effects of adenosine i.e. increase in blood pressure and heart rate and also increase pain response (angina-pectoris type chest pain) provoked by adenosine administration.

4.6 Fertility, Pregnancy and lactation

Pregnancy

Stopping smoking is the single most effective intervention for improving the health of both the pregnant smoker and her baby, and the earlier abstinence is achieved the better. Ideally smoking cessation during pregnancy should be achieved without NRT. Nicotine passes to the foetus and affects its breathing movements and circulation. The effect on the circulation is dose-dependent. However, if the mother cannot (or is considered unlikely to) quit without pharmacological support, NRT may be used as the risk to the foetus is lower than that expected with smoking tobacco. Stopping completely is by far the best option but if this is not achievable this product may be used in pregnancy as a safer alternative to smoking. Because of the potential for nicotine-free periods, intermittent dose forms are preferable, but patches may be considered as an alternative if there is significant nausea and/or vomiting. If patches are used they should, if possible, be removed at night when the foetus would not normally be exposed to nicotine.

There is no or limited data regarding the effect of vaping in pregnancy.

Use of NRT by the pregnant smoker/vaper should only be initiated after advice from a health care professional.

Lactation

Nicotine should be avoided during breast-feeding. The relatively small amounts of nicotine found in breast milk during NRT use are less hazardous to the infant than second-hand smoke. Intermittent dose forms would minimize the amount of nicotine in breast milk and permit feeding when levels were at their lowest.

There is no or limited data regarding the effect of vaping in lactating women.

Use of NRT by breast feeding smokers/vapers should only be initiated after advice from a health care professional. Women should use the product as soon as possible after breastfeeding.

Fertility

In females tobacco smoking delays time to conception, decreases in-vitro fertilization success rates, and significantly increases the risk of infertility.

In males tobacco smoking reduces sperm production, increases oxidative stress, and DNA damage. Spermatozoa from smokers have reduced fertilizing capacity.

The specific contribution of nicotine to these effects in humans is unknown.

There is no or limited data regarding the effect of vaping on fertility.

4.7 Effects on ability to drive and use machines

This product has no or negligible influence on the ability to drive and use machines**.**

4.8 Undesirable effects

Effects of Smoking Cessation

Some symptoms may be related to nicotine withdrawal associated with stopping smoking. These can include irritability/aggression, dysphoria/depressed mood, anxiety, restlessness, poor concentration, increased appetite/weight gain, urges to smoke (cravings), night-time awakenings/sleep disturbance, decreased heart rate, dizziness, presyncopal symptoms, cough, constipation, gingival bleeding or nasopharyngitis.

Increased frequency of aphthous ulcer may occur after abstinence from smoking. The causality is unclear.

Effects of Vaping Cessation

The nicotine withdrawal effects of vaping cessation have not been established; however it is anticipated that many of the effects relating to nicotine withdrawal will be the same as those seen with tobacco smoking cessation.

Adverse Drug Reactions

This product may cause adverse reactions similar to those associated with nicotine given by other means, including smoking and vaping, and these are mainly dose-dependent. At recommended doses this product has not been found to cause any serious adverse effects. Most of the undesirable effects reported by the patients occur during the first 3-4 weeks after start of treatment.

Excessive consumption of this product by those who have not been in the habit of inhaling tobacco smoke or vaping could possibly lead to nausea, faintness or headaches. Excessive swallowing of dissolved nicotine may, at first, cause hiccupping.

Nicotine from the gum may sometimes cause a slight irritation of the throat at the start of treatment, however most subjects adapt to this with ongoing use. This product may also cause increased salivation.

Allergic reactions (including symptoms of anaphylaxis) can occur during the use of the product.

Those who are prone to indigestion may suffer initially from minor degrees of indigestion or heartburn if the 4 mg nicotine gum is used; slower chewing and the use of the 2 mg nicotine gum (if necessary more frequently) will usually overcome this problem.

The chewing gum may stick to and may in rare cases damage dentures.

The adverse reactions observed in patients treated with oral nicotine formulations during clinical trials and post-marketing experience are listed below by system organ class (SOC). Frequencies are defined in accordance with current guidance, as: very common (>1/10); common (>1/100, <1/10); uncommon (>1/1 000, <1/100); rare (>1/10 000, <1/1 000); very rare (<1/10 000), not known - cannot be estimated from the available data.

System Organ Class	**Reported Adverse Event**	**Incidence**
Immune System Disorders	Hypersensitivity[a] Anaphylactic reaction[a]	Common Not known
Psychiatric Disorders	Abnormal dreams[*]	Uncommon
Nervous System Disorders	Headache[a#] Burning sensation[c] Dizziness Dysgeusia Paraesthesia[a] Seizures	Very common Common Common Common Common Not known
Eye Disorders	Blurred vision Lacrimation increased	Not known Not known
Cardiac Disorders	Palpitations[a] Tachycardia[a] Atrial fibrillation	Uncommon Uncommon Very rare
Vascular Disorders	Flushing[a] Hypertension[a]	Uncommon Uncommon
Respiratory, Thoracic and Mediastinal Disorders	Cough** Sore mouth or throat Throat irritation** Bronchospasm Dysphonia Dyspnoea[a] Nasal congestion Sneezing Throat tightness	Common Very common Very common Uncommon Uncommon Uncommon Uncommon Uncommon Uncommon
Gastrointestinal Disorders	Nausea[a] Hiccups**** Abdominal pain Diarrhoea[***] Dry mouth Flatulence Salivary hypersecretion Stomatitis Vomiting[a] Dyspepsia Eructation Glossitis Oral mucosal blistering and exfoliation	Very common Very common Common Common Common Common Common Common Common Common Uncommon Uncommon Uncommon

	Paraesthesia oral***	Uncommon
	Dysphagia	Rare
	Hypoaesthesia oral***	Rare
	Retching	Rare
	Dry throat	Not known
	Gastrointestinal discomfort[a]	Not known
	Lip pain	Not known
Skin and Subcutaneous Tissue Disorders	Urticaria[a]	Uncommon
	Hyperhidrosis[a]	Uncommon
	Pruritus[a]	Uncommon
	Rash[a]	Uncommon
	Erythema[a]	Not known
Musculoskeletal and Connective Tissue Disorders	Pain in jaw[b]	Uncommon
	Muscle tightness[b]	Not known
General Disorders and Administration Site Conditions	Fatigue[a]	Common
	Asthenia[a]	Uncommon
	Chest discomfort and pain[a]	Uncommon
	Malaise[a]	Uncommon
	Allergic reactions including angioedema	Rare

[a] Systemic effects; [b] Tightness of jaw and pain in jaw with nicotine gum formulation
[c] At the application site
*Identified only for formulations applied during the night
**Higher frequency observed in clinical studies with inhaler formulation.
***Reported the same or less frequently than placebo
****Higher frequency observed in clinical studies with mouth spray formulation
[#] Although the frequency in the active group is less than that of the placebo group, the frequency in the specific formulation in which the PT was identified as a systemic ADR was greater in the active group than the placebo group

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

4.9 Overdose

Symptoms: Symptoms of overdose with nicotine from this product may occur in smokers/vapers who have previously had a low nicotine intake from cigarettes/e-cigarettes or if other sources of nicotine are used concomitantly with this product.

Acute or chronic toxicity of nicotine in man is highly dependent on mode and route of administration. Adaptation to nicotine (e.g. in smokers/vapers) is known to significantly increase tolerability compared with non-smokers/vapers. The minimum lethal dose of nicotine in a non-tolerant man has been estimated to be 40 to 60 mg. Symptoms of acute nicotine poisoning include nausea, vomiting, increased salivation, abdominal pain, diarrhoea,

sweating, headache, dizziness, disturbed hearing and marked weakness. In extreme cases, these symptoms may be followed by hypotension, rapid or weak or irregular pulse, breathing difficulties, prostration, circulatory collapse and terminal convulsions.

Management of an overdose: All nicotine intake should stop immediately and the patient should be treated symptomatically. Artificial respiration should be instituted if necessary. Activated charcoal reduces the gastro-intestinal absorption of nicotine.

The risk of poisoning as a result of swallowing the gum is very small, as absorption in the absence of chewing is slow and incomplete.

Doses of nicotine that are tolerated by adult smokers/vapers during treatment may produce severe symptoms of poisoning in children and may prove fatal. Suspected nicotine poisoning in a child should be considered a medical emergency and treated immediately.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Drugs used in nicotine dependence
ATC code: N07B A01

The pharmacological effects of nicotine are well documented. Those resulting from chewing this product are comparatively small. The response at any one time represents a summation of stimulant and depressant actions from direct, reflex and chemical mediator influences on several organs. The main pharmacological actions are central stimulation and/or depression; transient hyperpnoea; peripheral vasoconstriction (usually associated with a rise in systolic pressure); suppression of appetite and stimulation of peristalsis.

Increased appetite is a recognised symptom of nicotine withdrawal and post-cessation weight gain is common. Clinical trials have demonstrated that Nicotine Replacement Therapy can help control weight following a quit attempt.

5.2 Pharmacokinetic properties

Nicotine administered in chewing gums is readily absorbed from the buccal mucous membranes. Demonstrable blood levels are obtained within 5 – 7 minutes and reach a maximum about 30 minutes after the start of chewing. Blood levels are roughly proportional to the amount of nicotine chewed and have been shown never to exceed those obtained from smoking cigarettes.

5.3 Preclinical safety data

Preclinical data indicate that nicotine is neither mutagenic nor genotoxic. There are no other findings derived from preclinical testing of relevance to the prescriber in determining the safety of the product which have not been

considered in other relevant sections of this Summary of Product Characteristics.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Core gum
Chewing gum base, containing butylated hydroxy toluene (E321)
Xylitol
Peppermint oil
Sodium carbonate, anhydrous
Sodium hydrogen carbonate
Acesulfame Potassium
Levomenthol
Magnesium oxide, light
Talc

Sub-coating
Tuttifrutti QL84441
Hypromellose
Sucralose
Polysorbate 80
Purified water

Coating
Xylitol
Acacia
Titanium dioxide (E171)
Tuttifrutti Ql84441
Carnauba wax
Purified water

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

Blister: 3 Years
Box: 3 Years. Shelf life after opening 3 months.

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container

PVC/PVDC/Al Blister packed strips each containing 15 pieces supplied in packs of 15, 30, 75, 105, 165 and 210 pieces.

Blister packed strips each containing 6 pieces supplied in packs of 12 pieces.
Blister packed strips each containing 10 pieces supplied in packs of 10 pieces.
and

Laminated cardboard box, wrapped in a transparent plastic film, containing 25 pieces, supplied in packs of 25, 100 and 200.

Each carton contains 25 pieces of gum and can be supplied in packs of 25, 100 or 200.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal

Dispose of Nicorette Gum sensibly.

Any unused product or waste material should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

McNeil Products Limited
1 Station Hill Square
Station Hill
Reading
RG1 1LN
UK

8 MARKETING AUTHORISATION NUMBER(S)

PL 15513/0136

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

28 August 2025

10 DATE OF REVISION OF THE TEXT

8 June 2026

SUMMARY OF PRODUCT CHATRACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Nicorette Fruitfusion 4 mg Gum
Boots NicAssist Fruit Fresh 4 mg Gum

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Chewing Gum containing 4 mg nicotine, as nicotine resinate.

Excipients with known effect:
Butylated hydroxytoluene

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Medicated Chewing Gum

A square, coated, crème coloured piece of gum

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

This product relieves and/or prevents craving and nicotine withdrawal symptoms in nicotine dependence such as those arising from the use of tobacco or electronic cigarettes. It is indicated to aid quitting or reduction prior to quitting, to assist those who are unwilling or unable to use such products, and as a safer alternative to smoking tobacco for smokers and those around them.

This product is indicated in pregnant and lactating women making a quit attempt.

4.2 Posology and method of administration

Adults and children over 12 years of age

This product should be chewed slowly according to the instructions.

The strength of gum to be used will depend on the smoking/vaping habits of the individual. In general, if the patient smokes 20 or less cigarettes a day, 2 mg nicotine gum is indicated. If more than 20 cigarettes per day are smoked, 4 mg nicotine gum will be needed to meet the withdrawal of the high serum nicotine levels from heavy smoking.

Light to moderate vapers (e.g. vape infrequently or use low strength e-liquid) should start with 2 mg nicotine gum. If the 2 mg nicotine gum does not relieve

the urge to vape, 4 mg nicotine gum should be used. Heavy vapers (e.g. vape frequently or use high strength e-liquid) should use 4 mg nicotine gum.

This product should be used whenever the urge to smoke or vape is felt or to prevent cravings in situations where these are likely to occur.

Patients willing or able to stop smoking/vaping immediately should initially replace all their cigarettes/e-cigarettes with the gum and as soon as they are able, reduce the number of gums used until they have stopped completely.

Patients aiming to reduce cigarettes/e-cigarettes should use this product between smoking/vaping episodes, as needed, to prolong smoke/vape-free intervals and to reduce their use as much as possible.

As soon as they are ready patients should aim to quit smoking/vaping completely.

Maximum daily dose: 15 pieces per day.

When making a quit attempt behavioural therapy, advice and support will normally improve the success rate. Those who have quit smoking/vaping but are having difficulty discontinuing this product are recommended to contact their pharmacist or doctor for advice.

For those using the 4 mg gum, switching to the 2 mg gum may be helpful when stopping treatment or reducing the number of gums used each day.

The chewing gums should be used whenever there is an urge to smoke/vape according to the "chew and rest" technique described on the pack. After about 30 minutes of such use, the gum will be exhausted. Absorption of nicotine is through the buccal mucosa, any nicotine which is swallowed being destroyed by the liver.

4.3 Contraindications

Hypersensitivity to nicotine or any component of the chewing gum.

This product is contraindicated in children under the age of 12 years.

4.4 Special warnings and precautions for use

Any risks that may be associated with NRT are substantially outweighed by the well-established dangers of continued smoking. The risks of continued vaping are not yet established.

A risk-benefit assessment should be made by an appropriate healthcare professional for patients with the following conditions:

Underlying cardiovascular disease: In stable cardiovascular disease this product presents a lesser hazard than continuing to smoke. However dependent smokers currently hospitalised as a result of myocardial infarction,

unstable or worsening angina including Prinzmetal angina, severe dysrhythmia or CVA and who are considered to be haemodynamically unstable and/or who suffer with uncontrolled hypertension should be encouraged to stop smoking with non-pharmacological interventions. If this fails, this product may be considered, but as data on safety in this patient group are limited, initiation should only be under medical supervision. The risks of continued vaping are not yet established.

Diabetes mellitus: Patients with diabetes mellitus should be advised to monitor their blood sugar levels more closely than usual when quitting and NRT is initiated as reductions in nicotine induced catecholamine release can affect carbohydrate metabolism.

GI disease: Nicotine may exacerbate symptoms in patients suffering from oesophagitis, gastritis or peptic ulcers and NRT preparations should be used with caution in these conditions. Ulcerative stomatitis has been reported.

Renal or hepatic impairment: This product should be used with caution in patients with moderate to severe hepatic impairment and/or severe renal impairment as the clearance of nicotine or its metabolites may be decreased with the potential for increased adverse effects.

Seizures: Potential risks and benefits of nicotine should be carefully evaluated before use in subjects with a history of epilepsy as cases of convulsions have been reported in association with nicotine.

Danger in children: Doses of nicotine tolerated by adult and adolescent smokers or vapers can produce severe toxicity in children that may be fatal. Products containing nicotine should not be left where they may be misused, handled or ingested by children. Nicotine gum should be disposed of with care.

Phaeochromocytoma and uncontrolled hyperthyroidism: As nicotine causes release of catecholamines, this product should be used with caution in patients with uncontrolled hyperthyroidism or phaeochromocytoma.

Transferred dependence: Transferred dependence is rare and is both less harmful and easier to break than smoking dependence.

Stopping smoking: Polycyclic aromatic hydrocarbons in tobacco smoke induce the metabolism of drugs metabolised by CYP 1A2 (and possibly by CYP 1A1). When a smoker stops smoking, this may result in slower metabolism and a consequent rise in blood levels of such drugs. This is of potential clinical importance for products with a narrow therapeutic window, e.g. theophylline, clozapine and ropinirole.

Excipients: This product also contains butylated hydroxy toluene (E321); this may cause irritation to the mucous membranes.

This medicine contains less than 1 mmol sodium (23 mg) in each chewing gum, that is to say essentially 'sodium- free'.

Denture warning: Patients who wear dentures may experience difficulty in chewing this product. The chewing gum may stick to and may in rare cases damage dentures.

4.5 Interaction with other medicinal products and other forms of interaction

No clinically relevant interactions between nicotine replacement therapy and other drugs have definitely been established. However nicotine may possibly enhance the haemodynamic effects of adenosine i.e. increase in blood pressure and heart rate and also increase pain response (angina-pectoris type chest pain) provoked by adenosine administration.

4.6 Fertility, Pregnancy and lactation

Pregnancy

Stopping smoking is the single most effective intervention for improving the health of both the pregnant smoker and her baby, and the earlier abstinence is achieved the better. Ideally smoking cessation during pregnancy should be achieved without NRT. Nicotine passes to the foetus and affects its breathing movements and circulation. The effect on the circulation is dose-dependent. However, if the mother cannot (or is considered unlikely to) quit without pharmacological support, NRT may be used as the risk to the foetus is lower than that expected with smoking tobacco. Stopping completely is by far the best option but if this is not achievable this product may be used in pregnancy as a safer alternative to smoking. Because of the potential for nicotine-free periods, intermittent dose forms are preferable, but patches may be considered as an alternative if there is significant nausea and/or vomiting. If patches are used they should, if possible, be removed at night when the foetus would not normally be exposed to nicotine.

There is no or limited data regarding the effect of vaping in pregnancy.

Use of NRT by the pregnant smoker/vaper should only be initiated after advice from a health care professional.

Lactation

Nicotine should be avoided during breast-feeding. The relatively small amounts of nicotine found in breast milk during NRT use are less hazardous to the infant than second-hand smoke. Intermittent dose forms would minimize the amount of nicotine in breast milk and permit feeding when levels were at their lowest.

There is no or limited data regarding the effect of vaping in lactating women.

Use of NRT by breast feeding smokers/vapers should only be initiated after advice from a health care professional. Women should use the product as soon as possible after breastfeeding.

Fertility
In females tobacco smoking delays time to conception, decreases in-vitro fertilization success rates, and significantly increases the risk of infertility.

In males tobacco smoking reduces sperm production, increases oxidative stress, and DNA damage. Spermatozoa from smokers have reduced fertilizing capacity.

The specific contribution of nicotine to these effects in humans is unknown.

There is no or limited data regarding the effect of vaping on fertility.

4.7 Effects on ability to drive and use machines

This product has no or negligible influence on the ability to drive and use machines**.**

4.8 Undesirable effects

Effects of Smoking Cessation

Some symptoms may be related to nicotine withdrawal associated with stopping smoking. These can include irritability/aggression, dysphoria/depressed mood, anxiety, restlessness, poor concentration, increased appetite/weight gain, urges to smoke (cravings), night-time awakenings/sleep disturbance, decreased heart rate, dizziness, presyncopal symptoms, cough, constipation, gingival bleeding or nasopharyngitis.

Increased frequency of aphthous ulcer may occur after abstinence from smoking. The causality is unclear.

Effects of Vaping Cessation

The nicotine withdrawal effects of vaping cessation have not been established; however it is anticipated that many of the effects relating to nicotine withdrawal will be the same as those seen with tobacco smoking cessation.

Adverse Drug Reactions

This product may cause adverse reactions similar to those associated with nicotine given by other means, including smoking and vaping, and these are mainly dose-dependent. At recommended doses this product has not been found to cause any serious adverse effects. Most of the undesirable effects reported by the patients occur during the first 3-4 weeks after start of treatment.

Excessive consumption of this product by those who have not been in the habit of inhaling tobacco smoke or vaping could possibly lead to nausea, faintness or headaches. Excessive swallowing of dissolved nicotine may, at first, cause hiccupping.

Nicotine from the gum may sometimes cause a slight irritation of the throat at the start of treatment, however most subjects adapt to this with ongoing use. This product may also cause increased salivation.

Allergic reactions (including symptoms of anaphylaxis) can occur during the use of the product.

Those who are prone to indigestion may suffer initially from minor degrees of indigestion or heartburn if the 4 mg nicotine gum is used; slower chewing and the use of the 2 mg nicotine gum (if necessary more frequently) will usually overcome this problem.

The chewing gum may stick to and may in rare cases damage dentures.

The adverse reactions observed in patients treated with oral nicotine formulations during clinical trials and post-marketing experience are listed below by system organ class (SOC). Frequencies are defined in accordance with current guidance, as: very common (>1/10); common (>1/100, <1/10); uncommon (>1/1 000, <1/100); rare (>1/10 000, <1/1 000); very rare (<1/10 000), not known - cannot be estimated from the available data.

System Organ Class	**Reported Adverse Event**	**Incidence**
Immune System Disorders	Hypersensitivity[a] Anaphylactic reaction[a]	Common Not known
Psychiatric Disorders	Abnormal dreams[*]	Uncommon
Nervous System Disorders	Headache[a#] Burning sensation[c] Dizziness Dysgeusia Paraesthesia[a] Seizures	Very common Common Common Common Common Not known
Eye Disorders	Blurred vision Lacrimation increased	Not known Not known
Cardiac Disorders	Palpitations[a] Tachycardia[a] Atrial fibrillation	Uncommon Uncommon Very rare
Vascular Disorders	Flushing[a] Hypertension[a]	Uncommon Uncommon
Respiratory, Thoracic and Mediastinal Disorders	Cough** Sore mouth or throat Throat irritation** Bronchospasm Dysphonia Dyspnoea[a] Nasal congestion Sneezing Throat tightness	Common Very common Very common Uncommon Uncommon Uncommon Uncommon Uncommon Uncommon
Gastrointestinal Disorders	Nausea[a] Hiccups****	Very common Very common

	Abdominal pain Diarrhoea*** Dry mouth Flatulence Salivary hypersecretion Stomatitis Vomiting[a] Dyspepsia Eructation Glossitis Oral mucosal blistering and exfoliation Paraesthesia oral*** Dysphagia Hypoaesthesia oral*** Retching Dry throat Gastrointestinal discomfort[a] Lip pain	Common Common Common Common Common Common Common Common Uncommon Uncommon Uncommon Uncommon Rare Rare Rare Not known Not known Not known
Skin and Subcutaneous Tissue Disorders	Urticaria[a] Hyperhidrosis[a] Pruritus[a] Rash[a] Erythema[a]	Uncommon Uncommon Uncommon Uncommon Not known
Musculoskeletal and Connective Tissue Disorders	Pain in Jaw[b] Muscle tightness[b]	Uncommon Not known
General Disorders and Administration Site Conditions	Fatigue[a] Asthenia[a] Chest discomfort and pain[a] Malaise[a] Allergic reactions including angioedema	Common Uncommon Uncommon Uncommon Rare

[a] Systemic effects; [b] Tightness of jaw and pain in jaw with nicotine gum formulation
[c] At the application site
*Identified only for formulations applied during the night
**Higher frequency observed in clinical studies with inhaler formulation.
***Reported the same or less frequently than placebo
**** Higher frequency observed in clinical studies with mouth spray formulation
[#] Although the frequency in the active group is less than that of the placebo group, the frequency in the specific formulation in which the PT was identified as a systemic ADR was greater in the active group than the placebo group.

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

4.9 Overdose

Symptoms: Symptoms of overdose with nicotine from this product may occur in smokers/vapers who have previously had a low nicotine intake from cigarettes/e-cigarettes or if other sources of nicotine are used concomitantly with this product.

Acute or chronic toxicity of nicotine in man is highly dependent on mode and route of administration. Adaptation to nicotine (e.g. in smokers/vapers) is known to significantly increase tolerability compared with non-smokers/vapers. The minimum lethal dose of nicotine in a non-tolerant man has been estimated to be 40 to 60 mg. Symptoms of acute nicotine poisoning include nausea, vomiting, increased salivation, abdominal pain, diarrhoea, sweating, headache, dizziness, disturbed hearing and marked weakness. In extreme cases, these symptoms may be followed by hypotension, rapid or weak or irregular pulse, breathing difficulties, prostration, circulatory collapse and terminal convulsions.

Management of an overdose: All nicotine intake should stop immediately and the patient should be treated symptomatically. Artificial respiration should be instituted if necessary. Activated charcoal reduces the gastro-intestinal absorption of nicotine.

The risk of poisoning as a result of swallowing the gum is very small, as absorption in the absence of chewing is slow and incomplete.

Doses of nicotine that are tolerated by adult smokers/vapers during treatment may produce severe symptoms of poisoning in children and may prove fatal. Suspected nicotine poisoning in a child should be considered a medical emergency and treated immediately.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Drugs used in nicotine dependence
ATC code: N07B A01

The pharmacological effects of nicotine are well documented. Those resulting from chewing this product are comparatively small. The response at any one time represents a summation of stimulant and depressant actions from direct, reflex and chemical mediator influences on several organs. The main pharmacological actions are central stimulation and/or depression; transient hyperpnoea; peripheral vasoconstriction (usually associated with a rise in systolic pressure); suppression of appetite and stimulation of peristalsis.

Increased appetite is a recognised symptom of nicotine withdrawal and post-cessation weight gain is common. Clinical trials have demonstrated that Nicotine Replacement Therapy can help control weight following a quit attempt.

5.2 Pharmacokinetic properties

Nicotine administered in chewing gums is readily absorbed from the buccal mucous membranes. Demonstrable blood levels are obtained within 5 – 7 minutes and reach a maximum about 30 minutes after the start of chewing. Blood levels are roughly proportional to the amount of nicotine chewed and have been shown never to exceed those obtained from smoking cigarettes.

5.3 Preclinical safety data

Preclinical data indicate that nicotine is neither mutagenic nor genotoxic. There are no other findings derived from preclinical testing of relevance to the prescriber in determining the safety of the product which have not been considered in other relevant sections of this Summary of Product Characteristics.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Core gum
Chewing gum base, containing butylated hydroxy toluene (E321)
Xylitol
Peppermint oil
Sodium carbonate, anhydrous
Acesulfame Potassium
Levomenthol
Magnesium oxide, light
Quinoline yellow Al-Lake (E104)
Talc

Sub-coating
Tuttifrutti QL84441
Hypromellose
Sucralose
Polysorbate 80
Purified water

Coating
Xylitol
Acacia
Titanium dioxide (E171)
Tuttifrutti QL84441
Quinoline yellow Al-lake (E104)
Carnauba wax
Purified Water

6.2 Incompatibilities
Not applicable.

6.3 Shelf life
Blister: 3 Years
Box: 3 Years. Shelf life after opening 3 months.

6.4 Special precautions for storage
Do not store above 25°C.

6.5 Nature and contents of container
PVC/PVDC/Al Blister packed strips each containing 15 pieces supplied in packs of 15, 30, 75, 105, 165 and 210 pieces.

Blister packed strips each containing 6 pieces supplied in packs of 12 pieces.
Blister packed strips each containing 10 pieces supplied in packs of 10 pieces.
and
Laminated cardboard box, wrapped in a transparent plastic film, containing 25 pieces, supplied in packs of 25, 100 and 200.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal
Dispose of Nicorette Gum sensibly.

Any unused product or waste material should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER
McNeil Products Limited
1 Station Hill Square
Station Hill
Reading
RG1 1LN
UK

8 MARKETING AUTHORISATION NUMBER(S)
PL 15513/0137

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION
28 August 2025

10 DATE OF REVISION OF THE TEXT

8 Jun 2026

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Nicorette Freshmint 2 mg Gum or NicAssist Minty Fresh 2 mg Gum

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Chewing Gum containing 2 mg nicotine, as nicotine resinate.

For excipients see section 6.1

3 PHARMACEUTICAL FORM

Medicated Chewing Gum

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Nicorette Freshmint 2 mg Gum relieves and/or prevents craving and nicotine withdrawal symptoms in nicotine dependence such as those arising from the use of tobacco or electronic cigarettes. It is indicated to aid quitting or reduction prior to quitting, to assist those who are unwilling or unable to use such products, and as a safer alternative to smoking tobacco for smokers and those around them.

Nicorette Freshmint 2 mg Gum is indicated in pregnant and lactating women making a quit attempt.

4.2 Posology and method of administration

Adults and children over 12 years of age

Nicorette Freshmint 2 mg Gum should be chewed slowly according to the instructions.

The strength of gum to be used will depend on the smoking/vaping habits of the individual. In general, if the patient smokes 20 or less cigarettes a day, 2 mg nicotine gum is indicated. If more than 20 cigarettes per day are smoked, 4 mg nicotine gum will be needed to meet the withdrawal of the high serum nicotine levels from heavy smoking.

Light to moderate vapers (e.g. vape infrequently or use low strength e-liquid) low strength e-liquid) should start with 2 mg nicotine gum. If the 2 mg nicotine gum does not relieve the urge to vape, 4 mg nicotine gum should be used. Heavy vapers (e.g. vape frequently or used high strength e-liquid) should use 4 mg nicotine gum.

Nicorette Freshmint 2 mg Gum should be used whenever the urge to smoke or vape is felt or to prevent cravings in situations where these are likely to occur.

Patients willing or able to stop smoking/vaping immediately should initially replace all their cigarettes/e-cigarettes with the gum and as soon as they are able, reduce the number of gums used until they have stopped completely.

Patients aiming to reduce cigarettes/e-cigarettes should use Nicorette Freshmint 2 mg Gum between smoking/vaping episodes, as needed, to prolong smoke/vape-free intervals and to reduce their use as much as possible.

As soon as they are ready patients should aim to quit smoking/vaping completely.

Maximum daily dose: 15 pieces per day.

When making a quit attempt behavioural therapy, advice and support will normally improve the success rate. Those who have quit smoking/ vaping but are having difficulty discontinuing Nicorette Freshmint 2 mg Gum are recommended to contact their pharmacist or doctor for advice.

For those using the 4 mg gum, switching to the 2 mg gum may be helpful when stopping treatment or reducing the number of gums used each day.

The chewing gums should be used whenever there is an urge to smoke/vape according to the "chew and rest" technique described on the pack. After about 30 minutes of such use, the gum will be exhausted. Absorption of nicotine is through the buccal mucosa, any nicotine which is swallowed being destroyed by the liver.

4.3 Contraindications

Hypersensitivity to nicotine or any component of the chewing gum.

Nicorette Freshmint 2 mg Gum is contraindicated in children under the age of 12 years.

4.4 Special warnings and precautions for use

Any risks that may be associated with NRT are substantially outweighed by the well-established dangers of continued smoking. The risks of continued vaping are not yet established.

A risk-benefit assessment should be made by an appropriate healthcare professional for patients with the following conditions:

Underlying cardiovascular disease: In stable cardiovascular disease this product presents a lesser hazard than continuing to smoke. However dependent smokers currently hospitalised as a result of myocardial infarction, unstable or worsening angina including Prinzmetal angina, severe dysrhythmia or CVA and who are considered to be haemodynamically unstable and/or who suffer with uncontrolled hypertension should be encouraged to stop smoking with non-pharmacological interventions. If this fails, this product may be considered, but as data on safety in this patient

group are limited, initiation should only be under medical supervision. The risks of continued vaping are not yet established.

Diabetes mellitus: Patients with diabetes mellitus should be advised to monitor their blood sugar levels more closely than usual when quitting and NRT is initiated as reductions in nicotine induced catecholamine release can affect carbohydrate metabolism.

GI disease: Nicotine may exacerbate symptoms in patients suffering from oesophagitis, gastritis or peptic ulcers and NRT preparations should be used with caution in these conditions. Ulcerative stomatitis has been reported.

Renal or hepatic impairment: This product should be used with caution in patients with moderate to severe hepatic impairment and/or severe renal impairment as the clearance of nicotine or its metabolites may be decreased with the potential for increased adverse effects.

Seizures: Potential risks and benefits of nicotine should be carefully evaluated before use in subjects with a history of epilepsy as cases of convulsions have been reported in association with nicotine.

Danger in children: Doses of nicotine tolerated by adult and adolescent smokers or vapers can produce severe toxicity in children that may be fatal. Products containing nicotine should not be left where they may be misused, handled or ingested by children. Nicotine gum should be disposed of with care.

Phaeochromocytoma and uncontrolled hyperthyroidism: As nicotine causes release of catecholamines, this product should be used with caution in patients with uncontrolled hyperthyroidism or phaeochromocytoma.

Transferred dependence: Transferred dependence is rare and is both less harmful and easier to break than smoking dependence.

Stopping smoking: Polycyclic aromatic hydrocarbons in tobacco smoke induce the metabolism of drugs metabolised by CYP 1A2 (and possibly by CYP 1A1). When a smoker stops smoking, this may result in slower metabolism and a consequent rise in blood levels of such drugs. This is of potential clinical importance for products with a narrow therapeutic window, e.g. theophylline, clozapine and ropinirole.

Excipients: This product also contains butylated hydroxy toluene (E321); this may cause irritation to the mucous membranes.

Denture warning: Patients who wear dentures may experience difficulty in chewing this product. The chewing gum may stick to and may in rare cases damage dentures.

4.5 Interaction with other medicinal products and other forms of interactions

No clinically relevant interactions between nicotine replacement therapy and other drugs have definitely been established. However nicotine may possibly enhance the haemodynamic effects of adenosine i.e. increase in blood pressure and heart rate and also increase pain response (angina-pectoris type chest pain) provoked by adenosine administration.

4.6 Fertility, pregnancy and lactation

Pregnancy

Stopping smoking is the single most effective intervention for improving the health of both the pregnant smoker and her baby, and the earlier abstinence is achieved the better. Ideally smoking cessation during pregnancy should be achieved without NRT. Nicotine passes to the foetus and affects its breathing movements and circulation. The effect on the circulation is dose-dependent. However, if the mother cannot (or is considered unlikely to) quit without pharmacological support, NRT may be used as the risk to the foetus is lower than that expected with smoking tobacco. Stopping completely is by far the best option but if this is not achievable this product may be used in pregnancy as a safer alternative to smoking. Because of the potential for nicotine-free periods, intermittent dose forms are preferable, but patches may be considered as an alternative if there is significant nausea and/or vomiting. If patches are used they should, if possible, be removed at night when the foetus would not normally be exposed to nicotine.

There is no or limited data regarding the effect of vaping in pregnancy.

Use of NRT by the pregnant smoker/vaper should only be initiated after advice from a health care professional.

Lactation

Nicotine should be avoided during breast-feeding. The relatively small amounts of nicotine found in breast milk during NRT use are less hazardous to the infant than second-hand smoke. Intermittent dose forms would minimize the amount of nicotine in breast milk and permit feeding when levels were at their lowest.

There is no or limited data regarding the effect of vaping in lactating women.

Use of NRT by breast feeding smokers/vapers should only be initiated after advice from a health care professional. Women should use the product as soon as possible after breastfeeding.

Fertility

In females tobacco smoking delays time to conception, decreases in-vitro fertilization success rates, and significantly increases the risk of infertility.

In males tobacco smoking reduces sperm production, increases oxidative stress, and DNA damage. Spermatozoa from smokers have reduced fertilizing capacity.

The specific contribution of nicotine to these effects in humans is unknown.

There is no or limited data regarding the effect of vaping on fertility.

4.7 Effects on ability to drive and use machines

This product has no or negligible influence on the ability to drive and use machines.

4.8 Undesirable effects

Effects of Smoking Cessation

Some symptoms may be related to nicotine withdrawal associated with stopping smoking. These can include irritability/aggression, dysphoria/depressed mood, anxiety, restlessness, poor concentration, increased appetite/weight gain, urges to smoke (cravings), night-time awakenings/sleep disturbance, decreased heart rate, dizziness, presyncopal symptoms, cough, constipation, gingival bleeding or nasopharyngitis.

Increased frequency of aphthous ulcer may occur after abstinence from smoking. The causality is unclear.

Effects of Vaping Cessation

The nicotine withdrawal effects of vaping cessation have not been established; however it is anticipated that many of the effects relating to nicotine withdrawal will be the same as those seen with tobacco smoking cessation.

Adverse Drug Reactions

This product may cause adverse reactions similar to those associated with nicotine given by other means, including smoking and vaping, and these are mainly dose-dependent. At recommended doses this product has not been found to cause any serious adverse effects. Most of the undesirable effects reported by the patients occur during the first 3-4 weeks after start of treatment.

Excessive consumption of this product by those who have not been in the habit of inhaling tobacco smoke or vaping could possibly lead to nausea, faintness or headaches. Excessive swallowing of dissolved nicotine may, at first, cause hiccupping.

Nicotine from the gum may sometimes cause a slight irritation of the throat at the start of treatment, however most subjects adapt to this with ongoing use. This product may also cause increased salivation.

Allergic reactions (including symptoms of anaphylaxis) can occur during the use of the product.

Those who are prone to indigestion may suffer initially from minor degrees of indigestion or heartburn if the 4 mg nicotine gum is used; slower chewing and the use of the 2 mg nicotine gum (if necessary more frequently) will usually overcome this problem.

The chewing gum may stick to and may in rare cases damage dentures.

The adverse reactions observed in patients treated with oral nicotine formulations during clinical trials and post-marketing experience are listed below by system organ class (SOC). Frequencies are defined in accordance with current guidance, as: very common (>1/10); common (>1/100, <1/10); uncommon (>1/1 000, <1/100); rare (>1/10 000, <1/1 000); very rare (<1/10 000), not known - cannot be estimated from the available data.

System Organ Class	**Reported Adverse Event**	**Incidence**
Immune System Disorders	Hypersensitivity[a] Anaphylactic reaction[a]	Common Not known
Psychiatric Disorders	Abnormal dreams[*]	Uncommon
Nervous System Disorders	Headache[a#] Burning sensation[c] Dizziness Dysgeusia Paraesthesia[a] Seizures	Very common Common Common Common Common Not known
Eye Disorders	Blurred vision Lacrimation increased	Not known Not known
Cardiac Disorders	Palpitations[a] Tachycardia[a] Atrial fibrillation	Uncommon Uncommon Very rare
Vascular Disorders	Flushing[a] Hypertension[a]	Uncommon Uncommon
Respiratory, Thoracic and Mediastinal Disorders	Cough** Sore mouth or throat Throat irritation** Bronchospasm Dysphonia Dyspnoea[a] Nasal congestion Sneezing Throat tightness	Common Very common Very common Uncommon Uncommon Uncommon Uncommon Uncommon Uncommon
Gastrointestinal Disorders	Nausea[a] Hiccups**** Abdominal pain Diarrhoea[***] Dry mouth Flatulence Salivary hypersecretion Stomatitis Vomiting[a] Dyspepsia Eructation Glossitis Oral mucosal blistering and exfoliation	Very common Very common Common Common Common Common Common Common Common Common Uncommon Uncommon Uncommon

	Paraesthesia oral***	Uncommon
	Dysphagia	Rare
	Hypoaesthesia oral***	Rare
	Retching	Rare
	Dry throat	Not known
	Gastrointestinal discomfort[a]	Not known
	Lip pain	Not known
Skin and Subcutaneous Tissue Disorders	Urticaria[a]	Uncommon
	Hyperhidrosis[a]	Uncommon
	Pruritus[a]	Uncommon
	Rash[a]	Uncommon
	Erythema[a]	Not known
Musculoskeletal and Connective Tissue Disorders	Pain in jaw[b]	Uncommon
	Muscle tightness[b]	Not known
General Disorders and Administration Site Conditions	Fatigue[a]	Common
	Asthenia[a]	Uncommon
	Chest discomfort and pain[a]	Uncommon
	Malaise[a]	Uncommon
	Allergic reactions including angioedema	Rare

[a] Systemic effects; [b] Tightness of jaw and pain in jaw with nicotine gum formulation
[c] At the application site
*Identified only for formulations applied during the night
**Higher frequency observed in clinical studies with inhaler formulation.
***Reported the same or less frequently than placebo
**** Higher frequency observed in clinical studies with mouth spray formulation
[#] Although the frequency in the active group is less than that of the placebo group, the frequency in the specific formulation in which the PT was identified as a systemic ADR was greater in the active group than the placebo group.

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store**.**

4.9 Overdose

Symptoms: Symptoms of overdose with nicotine from this product may occur in smokers/vapers who have previously had a low nicotine intake from cigarettes/e-cigarettes or if other sources of nicotine are used concomitantly with this product.

Acute or chronic toxicity of nicotine in man is highly dependent on mode and route of administration. Adaptation to nicotine (e.g., in smokers/vapers) is known to significantly increase tolerability compared with non-smokers/vapers. The minimum lethal dose of nicotine in a non-tolerant man has been estimated to be 40 to 60 mg. Symptoms of acute nicotine poisoning

include nausea, vomiting, increased salivation, abdominal pain, diarrhoea, sweating, headache, dizziness, disturbed hearing and marked weakness. In extreme cases, these symptoms may be followed by hypotension, rapid or weak or irregular pulse, breathing difficulties, prostration, circulatory collapse and terminal convulsions.

Management of an overdose: All nicotine intake should stop immediately, and the patient should be treated symptomatically. Artificial respiration should be instituted if necessary. Activated charcoal reduces the gastro-intestinal absorption of nicotine.

The risk of poisoning as a result of swallowing the gum is very small, as absorption in the absence of chewing is slow and incomplete.

Doses of nicotine that are tolerated by adult smokers/vapers during treatment may produce severe symptoms of poisoning in children and may prove fatal. Suspected nicotine poisoning in a child should be considered a medical emergency and treated immediately.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Drugs used in nicotine dependence
ATC code: N07B A01

The pharmacological effects of nicotine are well documented. Those resulting from chewing Nicorette Freshmint 2 mg Gum are comparatively small. The response at any one time represents a summation of stimulant and depressant actions from direct, reflex and chemical mediator influences on several organs. The main pharmacological actions are central stimulation and/or depression; transient hyperpnoea; peripheral vasoconstriction (usually associated with a rise in systolic pressure); suppression of appetite and stimulation of peristalsis.

Increased appetite is a recognised symptom of nicotine withdrawal and post-cessation weight gain is common. Clinical trials have demonstrated that Nicotine Replacement Therapy can help control weight following a quit attempt.

5.2 Pharmacokinetic properties

Nicotine administered in chewing gums is readily absorbed from the buccal mucous membranes. Demonstrable blood levels are obtained within 5 – 7 minutes and reach a maximum about 30 minutes after the start of chewing. Blood levels are roughly proportional to the amount of nicotine chewed and have been shown never to exceed those obtained from smoking cigarettes.

5.3 Preclinical safety data

Preclinical data indicate that nicotine is neither mutagenic nor genotoxic.

There are no other findings derived from preclinical testing of relevance to the prescriber in determining the safety of the product which have not been considered in other relevant sections of this Summary of Product Characteristics.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Core Gum
Polacrilin
Chewing gum base, containing butylated hydroxy toluene (E321)
Xylitol
Peppermint oil
Sodium carbonate, anhydrous
Sodium bicarbonate
Acesulfame Potassium
Levomenthol
Magnesium oxide, light
Talcum
Nitrogen, food grade

Coating
Xylitol
Peppermint oil
Acacia
Titanium dioxide (E171)
Carnauba wax

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

Blister: 3 Years
Box: 3 Years. Shelf life after opening 3 months.

6.4 Special precautions for storage

Do not store above 25°C

6.5 Nature and contents of container

PVC/PVDC/Al Blister packed strips each containing 15 pieces supplied in packs of 15, 30, 105 and 210 pieces.

Blister packed strips each containing 6 pieces supplied in packs of 12 pieces.

Blister packed strips each containing 10 pieces supplied in packs of 10 pieces.
and
Laminated cardboard box, wrapped in a transparent plastic film, containing 25 pieces, supplied in packs of 25, 100 and 200.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal

Dispose of Nicorette Gum sensibly.
Any unused product or waste material should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

McNeil Products Limited
1 Station Hill Square
Station Hill
Reading
RG1 1LN
UK

8 MARKETING AUTHORISATION NUMBER(S)

PL 15513/0173

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

21/01/2008

10 DATE OF REVISION OF THE TEXT

13 April 2026

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Nicorette Freshmint 4 mg Gum
NicAssist Minty Fresh 4 mg Gum

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Chewing Gum containing 4 mg nicotine, as nicotine resinate.
For excipients see section 6.1

3 PHARMACEUTICAL FORM

Medicated Chewing Gum

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Nicorette Freshmint 4 mg Gum relieves and/or prevents craving and nicotine withdrawal symptoms in nicotine dependence such as those arising from the use of tobacco or electronic cigarettes. It is indicated to aid quitting or reduction prior to quitting, to assist those who are unwilling or unable to use such products, and as a safer alternative to smoking tobacco for smokers and those around them.

Nicorette Freshmint 4 mg Gum is indicated in pregnant and lactating women making a quit attempt.

4.2 Posology and method of administration

Adults and children over 12 years of age
Nicorette Freshmint 4 mg Gum should be chewed slowly according to the instructions.

The strength of gum to be used will depend on the smoking/vaping habits of the individual. In general, if the patient smokes 20 or less cigarettes a day, 2 mg nicotine gum is indicated. If more than 20 cigarettes per day are smoked, 4 mg nicotine gum will be needed to meet the withdrawal of the high serum nicotine levels from heavy smoking.

Light to moderate vapers (e.g. vape infrequently or use low strength e-liquid) should start with 2 mg nicotine gum. If the 2 mg nicotine gum does not relieve the urge to vape, 4 mg nicotine gum should be used. Heavy vapers (e.g. vape frequently or use high strength e-liquid) should use 4 mg nicotine gum.

Nicorette Freshmint 4 mg Gum should be used whenever the urge to smoke or vape is felt or to prevent cravings in situations where these are likely to occur.

Patients willing or able to stop smoking/vaping immediately should initially replace all their cigarettes/e-cigarettes with the gum and as soon as they are able, reduce the number of gums used until they have stopped completely.

Patients aiming to reduce cigarettes/e-cigarettes should use Nicorette Freshmint 4 mg Gum between smoking/vaping episodes, as needed, to prolong smoke/vape-free intervals and to reduce their use as much as possible.

As soon as they are ready patients should aim to quit smoking/vaping completely.

Maximum daily dose: 15 pieces per day.

When making a quit attempt behavioural therapy, advice and support will normally improve the success rate. Those who have quit smoking/vaping but are having difficulty discontinuing Nicorette Freshmint 4 mg Gum are recommended to contact their pharmacist or doctor for advice.

For those using the 4 mg gum, switching to the 2 mg gum may be helpful when stopping treatment or reducing the number of gums used each day**.**

The chewing gums should be used whenever there is an urge to smoke/vape according to the "chew and rest" technique described on the pack. After about 30 minutes of such use, the gum will be exhausted. Absorption of nicotine is through the buccal mucosa, any nicotine which is swallowed being destroyed by the liver.

4.3 Contraindications

Hypersensitivity to nicotine or any component of the chewing gum.

Nicorette Freshmint 4 mg Gum is contraindicated in children under the age of 12 years.

4.4 Special warnings and precautions for use

Any risks that may be associated with NRT are substantially outweighed by the well-established dangers of continued smoking. The risks of continued vaping are not yet established.

A risk-benefit assessment should be made by an appropriate healthcare professional for patients with the following conditions:

Underlying cardiovascular disease: In stable cardiovascular disease this product presents a lesser hazard than continuing to smoke. However dependent smokers currently hospitalised as a result of myocardial infarction, unstable or worsening angina including Prinzmetal angina, severe dysrhythmia or CVA and who are considered to be haemodynamically unstable and/or who suffer with uncontrolled hypertension should be encouraged to stop smoking with non-pharmacological interventions. If this fails, this product may be considered, but as data on safety in this patient

group are limited, initiation should only be under medical supervision. The risks of continued vaping are not yet established.

Diabetes mellitus: Patients with diabetes mellitus should be advised to monitor their blood sugar levels more closely than usual when quitting and NRT is initiated as reductions in nicotine induced catecholamine release can affect carbohydrate metabolism.

GI disease: Nicotine may exacerbate symptoms in patients suffering from oesophagitis, gastritis or peptic ulcers and NRT preparations should be used with caution in these conditions. Ulcerative stomatitis has been reported.

Renal or hepatic impairment: This product should be used with caution in patients with moderate to severe hepatic impairment and/or severe renal impairment as the clearance of nicotine or its metabolites may be decreased with the potential for increased adverse effects.

Seizures: Potential risks and benefits of nicotine should be carefully evaluated before use in subjects with a history of epilepsy as cases of convulsions have been reported in association with nicotine.

Danger in children: Doses of nicotine tolerated by adult and adolescent smokers or vapers can produce severe toxicity in children that may be fatal. Products containing nicotine should not be left where they may be misused, handled or ingested by children. Nicotine gum should be disposed of with care.

Phaeochromocytoma and uncontrolled hyperthyroidism: As nicotine causes release of catecholamines, this product should be used with caution in patients with uncontrolled hyperthyroidism or phaeochromocytoma.

Transferred dependence: Transferred dependence is rare and is both less harmful and easier to break than smoking dependence.

Stopping smoking: Polycyclic aromatic hydrocarbons in tobacco smoke induce the metabolism of drugs metabolised by CYP 1A2 (and possibly by CYP 1A1). When a smoker stops smoking, this may result in slower metabolism and a consequent rise in blood levels of such drugs. This is of potential clinical importance for products with a narrow therapeutic window, e.g. theophylline, clozapine and ropinirole.

Excipients: This product also contains butylated hydroxy toluene (E321); this may cause irritation to the mucous membranes.

Denture warning: Patients who wear dentures may experience difficulty in chewing this product. The chewing gum may stick to and may in rare cases damage dentures.

4.5 Interaction with other medicinal products and other forms of interactions

No clinically relevant interactions between nicotine replacement therapy and other drugs have definitely been established. However nicotine may possibly enhance the haemodynamic effects of adenosine i.e. increase in blood pressure and heart rate and also increase pain response (angina-pectoris type chest pain) provoked by adenosine administration.

4.6 Fertility, pregnancy and lactation

Pregnancy

Stopping smoking is the single most effective intervention for improving the health of both the pregnant smoker and her baby, and the earlier abstinence is achieved the better. Ideally smoking cessation during pregnancy should be achieved without NRT. Nicotine passes to the foetus and affects its breathing movements and circulation. The effect on the circulation is dose-dependent. However, if the mother cannot (or is considered unlikely to) quit without pharmacological support, NRT may be used as the risk to the foetus is lower than that expected with smoking tobacco. Stopping completely is by far the best option but if this is not achievable this product may be used in pregnancy as a safer alternative to smoking. Because of the potential for nicotine-free periods, intermittent dose forms are preferable, but patches may be considered as an alternative if there is significant nausea and/or vomiting. If patches are used they should, if possible, be removed at night when the foetus would not normally be exposed to nicotine.

There is no or limited data regarding the effect of vaping in pregnancy.

Use of NRT by the pregnant smoker/vaper should only be initiated after advice from a health care professional.

Lactation

Nicotine should be avoided during breast-feeding. The relatively small amounts of nicotine found in breast milk during NRT use are less hazardous to the infant than second-hand smoke. Intermittent dose forms would minimize the amount of nicotine in breast milk and permit feeding when levels were at their lowest.

There is no or limited data regarding the effect of vaping in lactating women.

Use of NRT by breast feeding smokers/vapers should only be initiated after advice from a health care professional. Women should use the product as soon as possible after breastfeeding.

Fertility

In females tobacco smoking delays time to conception, decreases in-vitro fertilization success rates, and significantly increases the risk of infertility.

In males tobacco smoking reduces sperm production, increases oxidative stress, and DNA damage. Spermatozoa from smokers have reduced fertilizing capacity.

The specific contribution of nicotine to these effects in humans is unknown.

There is no or limited data regarding the effect of vaping on fertility.

4.7 Effects on ability to drive and use machines

This product has no or negligible influence on the ability to drive and use machines.

4.8 Undesirable effects

Effects of Smoking Cessation

Some symptoms may be related to nicotine withdrawal associated with stopping smoking. These can include irritability/aggression, dysphoria/depressed mood, anxiety, restlessness, poor concentration, increased appetite/weight gain, urges to smoke (cravings), night-time awakenings/sleep disturbance, decreased heart rate, dizziness, presyncopal symptoms, cough, constipation, gingival bleeding or nasopharyngitis.

Increased frequency of aphthous ulcer may occur after abstinence from smoking. The causality is unclear.

Effects of Vaping Cessation

The nicotine withdrawal effects of vaping cessation have not been established; however it is anticipated that many of the effects relating to nicotine withdrawal will be the same as those seen with tobacco smoking cessation.

Adverse Drug Reactions

This product may cause adverse reactions similar to those associated with nicotine given by other means, including smoking and vaping, and these are mainly dose-dependent. At recommended doses this product has not been found to cause any serious adverse effects. Most of the undesirable effects reported by the patients occur during the first 3-4 weeks after start of treatment.

Excessive consumption of this product by those who have not been in the habit of inhaling tobacco smoke or vaping could possibly lead to nausea, faintness or headaches. Excessive swallowing of dissolved nicotine may, at first, cause hiccupping.

Nicotine from the gum may sometimes cause a slight irritation of the throat at the start of treatment, however most subjects adapt to this with ongoing use. This product may also cause increased salivation.

Allergic reactions (including symptoms of anaphylaxis) can occur during the use of the product.

Those who are prone to indigestion may suffer initially from minor degrees of indigestion or heartburn if the 4 mg nicotine gum is used; slower chewing and the use of the 2 mg nicotine gum (if necessary more frequently) will usually overcome this problem.

The chewing gum may stick to and may in rare cases damage dentures.

The adverse reactions observed in patients treated with oral nicotine formulations during clinical trials and post-marketing experience are listed below by system organ class (SOC). Frequencies are defined in accordance with current guidance, as: very common (>1/10); common (>1/100, <1/10); uncommon (>1/1 000, <1/100); rare (>1/10 000, <1/1 000); very rare (<1/10 000), not known - cannot be estimated from the available data.

System Organ Class	Reported Adverse Event	Incidence
Immune System Disorders	Hypersensitivity[a] Anaphylactic reaction[a]	Common Not known
Psychiatric Disorders	Abnormal dreams[*]	Uncommon
Nervous System Disorders	Headache[a#] Burning sensation[c] Dizziness Dysgeusia Paraesthesia[a] Seizures	Very common Common Common Common Common Not known
Eye Disorders	Blurred vision Lacrimation increased	Not known Not known
Cardiac Disorders	Palpitations[a] Tachycardia[a] Atrial fibrillation	Uncommon Uncommon Very rare
Vascular Disorders	Flushing[a] Hypertension[a]	Uncommon Uncommon
Respiratory, Thoracic and Mediastinal Disorders	Cough** Sore mouth or throat Throat irritation** Bronchospasm Dysphonia Dyspnoea[a] Nasal congestion Sneezing Throat tightness	Common Very common Very common Uncommon Uncommon Uncommon Uncommon Uncommon Uncommon
Gastrointestinal Disorders	Nausea[a] Hiccups**** Abdominal pain Diarrhoea[***] Dry mouth Flatulence Salivary hypersecretion Stomatitis Vomiting[a] Dyspepsia Eructation Glossitis Oral mucosal blistering and exfoliation Paraesthesia oral[***]	Very common Very common Common Common Common Common Common Common Common Common Uncommon Uncommon Uncommon Uncommon

	Dysphagia Hypoaesthesia oral*** Retching Dry throat Gastrointestinal discomfort[a] Lip pain	Rare Rare Rare Not known Not known Not known
Skin and Subcutaneous Tissue Disorders	Urticaria[a] Hyperhidrosis[a] Pruritus[a] Rash[a] Erythema[a]	Uncommon Uncommon Uncommon Uncommon Not known
Musculoskeletal and Connective Tissue Disorders	Pain in jaw[b] Muscle tightness[b]	Uncommon Not known
General Disorders and Administration Site Conditions	Fatigue[a] Asthenia[a] Chest discomfort and pain[a] Malaise[a] Allergic reactions including angioedema	Common Uncommon Uncommon Uncommon Rare

[a] Systemic effects; [b] Tightness of jaw and pain in jaw with nicotine gum formulation
[c] At the application site
*Identified only for formulations applied during the night
**Higher frequency observed in clinical studies with inhaler formulation.
***Reported the same or less frequently than placebo
**** Higher frequency observed in clinical studies with mouth spray formulation
[#] Although the frequency in the active group is less than that of the placebo group, the frequency in the specific formulation in which the PT was identified as a systemic ADR was greater in the active group than the placebo group.

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

4.9 Overdose

Symptoms: Symptoms of overdose with nicotine from this product may occur in smokers/vapers who have previously had a low nicotine intake from cigarettes/e-cigarettes or if other sources of nicotine are used concomitantly with this product.

Acute or chronic toxicity of nicotine in man is highly dependent on mode and route of administration. Adaptation to nicotine (e.g., in smokers/vapers) is known to significantly increase tolerability compared with non-smokers/vapers. The minimum lethal dose of nicotine in a non-tolerant man has been estimated to be 40 to 60 mg. Symptoms of acute nicotine poisoning include nausea, vomiting, increased salivation, abdominal pain, diarrhoea, sweating, headache, dizziness, disturbed hearing and marked weakness. In

extreme cases, these symptoms may be followed by hypotension, rapid or weak or irregular pulse, breathing difficulties, prostration, circulatory collapse and terminal convulsions.

Management of an overdose: All nicotine intake should stop immediately and the patient should be treated symptomatically. Artificial respiration should be instituted if necessary. Activated charcoal reduces the gastro-intestinal absorption of nicotine.

The risk of poisoning as a result of swallowing the gum is very small, as absorption in the absence of chewing is slow and incomplete.

Doses of nicotine that are tolerated by adult smokers/vapers during treatment may produce severe symptoms of poisoning in children and may prove fatal. Suspected nicotine poisoning in a child should be considered a medical emergency and treated immediately.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Drugs used in nicotine dependence
ATC code: N07B A01

The pharmacological effects of nicotine are well documented. Those resulting from chewing Nicorette Freshmint 4 mg Gum are comparatively small. The response at any one time represents a summation of stimulant and depressant actions from direct, reflex and chemical mediator influences on several organs. The main pharmacological actions are central stimulation and/or depression; transient hyperpnoea; peripheral vasoconstriction (usually associated with a rise in systolic pressure); suppression of appetite and stimulation of peristalsis.

Increased appetite is a recognised symptom of nicotine withdrawal and post-cessation weight gain is common. Clinical trials have demonstrated that Nicotine Replacement Therapy can help control weight following a quit attempt.

5.2 Pharmacokinetic properties

Nicotine administered in chewing gums is readily absorbed from the buccal mucous membranes. Demonstrable blood levels are obtained within 5 – 7 minutes and reach a maximum about 30 minutes after the start of chewing. Blood levels are roughly proportional to the amount of nicotine chewed and have been shown never to exceed those obtained from smoking cigarettes.

5.3 Preclinical safety data

Preclinical data indicate that nicotine is neither mutagenic nor genotoxic. There are no other findings derived from preclinical testing of relevance to the prescriber in determining the safety of the product which have not been

considered in other relevant sections of this Summary of Product Characteristics.

6 PHARMACEUTICAL PROPERTIES

6.1 List of excipients

Core Gum
Polacrilin
Chewing gum base, containing butylated hydroxy toluene (E321)
Xylitol
Peppermint oil
Sodium carbonate, anhydrous
Acesulfame Potassium
Levomenthol
Magnesium oxide, light
Quinoline yellow Al lake (E104)
Talcum
Nitrogen, food grade

Coating
Xylitol
Peppermint oil
Acacia
Titanium dioxide (E171)
Carnauba wax
Quinoline yellow Al lake (E104)

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

Blister: 3 Years

Box: 3 Years. Shelf life after opening 3 months.

6.4 Special precautions for storage

Do not store above 25°C

6.5 Nature and contents of container

Blister packed strips each containing 15 pieces supplied in packs of 15, 30, 105 and 210 pieces.

Blister packed strips each containing 6 pieces supplied in packs of 12 pieces.

Blister packed strips each containing 10 pieces supplied in packs of 10 pieces.

and

Laminated cardboard box, wrapped in a transparent plastic film, containing 25 pieces, supplied in packs of 25, 100 and 200.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal

Dispose of Nicorette Gum sensibly.
Any unused product or waste material should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

McNeil Products Limited
1 Station Hill Square
Station Hill
Reading
RG1 1LN
UK

8 MARKETING AUTHORISATION NUMBER(S)

PL 15513/0174

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

21/01/2008

10 DATE OF REVISION OF THE TEXT

13 April 2026

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Nicorette Cools 2 mg Lozenge

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each lozenge contains 2 mg nicotine (as nicotine resinate).
For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Compressed lozenge.

An oval, white to off-white lozenge imprinted with a “n” on one side and “2” on the other side.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Nicorette Cools 2 mg Lozenge relieves and/or prevents craving and nicotine withdrawal symptoms in nicotine dependence, such as those arising from the use of tobacco or electronic cigarettes. It is indicated to aid quitting or reduction prior to quitting, to assist those who are unwilling or unable to use such products, and as a safer alternative to smoking tobacco for smokers and those around them.

Nicorette Cools 2 mg Lozenge is indicated in pregnant and lactating women making a quit attempt.

4.2 Posology and method of administration

Adults and Children over 12 years of age
The strength of lozenge to be used will depend on the smoking/vaping habits of the individual. In general, if the patient smokes 20 or less cigarettes a day, 2 mg nicotine lozenge is indicated. If more than 20 cigarettes per day are smoked, 4 mg nicotine lozenge will be needed to meet the withdrawal of the high serum nicotine levels from heavy smoking.

Light to moderate vapers (e.g. vape infrequently or use low strength e-liquid) should start with 2 mg nicotine lozenge. If the 2 mg nicotine lozenge does not relieve the urge to vape, 4 mg nicotine lozenge should be used. Heavy vapers (e.g. vape frequently or use high strength e-liquid) should use 4 mg nicotine lozenge.

This product should be used whenever the urge to smoke or vape is felt or to prevent cravings in situations where these are likely to occur.

Patients willing or able to stop smoking/vaping immediately should initially replace all their cigarettes/e-cigarettes with the lozenge and as soon as they are able, reduce the number of lozenges used until they have stopped completely.

Patients aiming to reduce cigarettes/e-cigarettes should use the lozenge, , between smoking/vaping episodes, as needed, to prolong smoke/vape-free intervals and to reduce their use as much as possible.

As soon as they are ready patients should aim to quit smoking/vaping completely.

Most patients require 8 to 12 lozenges per day, not to exceed 15 lozenges.

When making a quit attempt behavioural therapy, advice and support will normally improve the success rate. Those who have quit smoking/vaping but are having difficulty discontinuing with the lozenge are recommended to contact their pharmacist or doctor for advice.

For those using the 4 mg lozenges, switching to the 2 mg lozenges may be helpful when stopping treatment or reducing the number of lozenges used each day.

Method of administration
One lozenge should be placed in the mouth and allowed to dissolve. Periodically, the lozenge should be moved from one side of the mouth to the other, and repeated, until the lozenge is completely dissolved. You should not chew or swallow the lozenge.

4.3 Contraindications

Hypersensitivity to any of components of the lozenge.
Nicorette Cools 2 mg Lozenge is contraindicated in children under the age of 12 years.

4.4 Special warnings and precautions for use

Any risks which may be associated with the use of NRT are substantially outweighed in virtually all circumstances by the well-established dangers of continued smoking. The risks of continued vaping are not yet established.
A risk-benefit assessment should be made by an appropriate healthcare professional for patients with the following conditions:

Underlying cardiovascular disease: In stable cardiovascular disease this product presents a lesser hazard than continuing to smoke. However dependent smokers currently hospitalised as a result of myocardial infarction, unstable or worsening angina including Prinzmetal angina, severe dysrhythmia or cerebrovascular accident and who are considered to be haemodynamically unstable and/or who have uncontrolled hypertension should be encouraged to stop smoking with

non-pharmacological interventions. If this fails, this product may be considered, but as data on safety in this patient group are limited, initiation should only be under medical supervision. The risks of continued vaping are not yet established.

Diabetes Mellitus: Patients with diabetes mellitus should be advised to monitor their blood sugar levels more closely than usual when quitting and NRT is initiated as reductions in nicotine induced catecholamine release can affect carbohydrate metabolism.

Renal and hepatic impairment: Use with caution in patients with moderate to severe hepatic impairment and/or severe renal impairment as the clearance of nicotine or its metabolites may be decreased with the potential for increased adverse effects.

Phaeochromocytoma and uncontrolled hyperthyroidism: Use with caution in patients with uncontrolled hyperthyroidism or phaeochromocytoma as nicotine causes release of catecholamines.

Gastrointestinal Disease: Nicotine may exacerbate symptoms in patients suffering from oesophagitis, gastric or peptic ulcers and NRT preparations should be used with caution in these conditions. Ulcerative stomatitis has been reported.

Seizures: Potential risks and benefits of nicotine should be carefully evaluated before use in subjects with a history of epilepsy as cases of convulsions have been reported in association with nicotine.

Danger in children: Doses of nicotine tolerated by adult and adolescent smokers or vapers can produce severe toxicity in children that may be fatal. Products containing nicotine should not be left where they may be misused, handled or ingested by children, see section 4.9 Overdose.

Transferred dependence: Transferred dependence is rare and is both less harmful and easier to break than smoking dependence.

Stopping smoking: Polycyclic aromatic hydrocarbons in tobacco smoke induce the metabolism of drugs metabolised by CYP 1A2 (and possibly by CYP 1A1). When a smoker stops smoking, this may result in slower metabolism and a consequent rise in blood levels of such drugs. This is of potential clinical importance for products with a narrow therapeutic window, e.g. theophylline, clozapine and ropinirole.

Choking hazard: Lozenges can represent a choking hazard, therefore keep out of the reach of children. Use with caution in individuals with aspiration and swallowing problems.

4.5 Interaction with other medicinal products and other forms of interaction

No clinically relevant interactions between nicotine replacement therapy and other drugs have definitely been established. However nicotine may possibly

enhance the haemodynamic effects of adenosine i.e. increase in blood pressure and heart rate and also increase pain response (angina-pectoris type chest pain) provoked by adenosine administration.

4.6 Fertility pregnancy and lactation

Pregnancy
Stopping smoking is the single most effective intervention for improving the health of both the pregnant smoker and her baby, and the earlier abstinence is achieved the better. Ideally smoking cessation during pregnancy should be achieved without NRT. Nicotine passes to the foetus and affects its breathing movements and circulation. The effect on the circulation is dose-dependent. However, if the mother cannot (or is considered unlikely to) quit without pharmacological support, NRT may be used as the risk to the foetus is lower than that expected with smoking tobacco. Stopping completely is by far the best option but if this is not achievable this product may be used in pregnancy as a safer alternative to smoking. Because of the potential for nicotine-free periods, intermittent dose forms are preferable, but patches may be considered as an alternative if there is significant nausea and/or vomiting. If patches are used they should, if possible, be removed at night when the foetus would not normally be exposed to nicotine.

There is no or limited data regarding the effect of vaping in pregnancy.

Use of NRT by the pregnant smoker/vaper should only be initiated after advice from a health care professional.

Lactation
Nicotine should be avoided during breast-feeding. The relatively small amounts of nicotine found in breast milk during NRT use are less hazardous to the infant than second-hand smoke. Intermittent dose forms would minimize the amount of nicotine in breast milk and permit feeding when levels were at their lowest. There is no or limited data regarding the effect of vaping in lactating women.

Use of NRT by breast feeding smokers/vapers should only be initiated after advice from a health care professional. Women should use the product as soon as possible after breastfeeding.

Fertility
In females tobacco smoking delays time to conception, decreases in-vitro fertilization success rates, and significantly increases the risk of infertility.

In males tobacco smoking reduces sperm production, increases oxidative stress, and DNA damage. Spermatozoa from smokers have reduced fertilizing capacity.

The specific contribution of nicotine to these effects in humans is unknown. There is no or limited data regarding the effect of vaping on fertility.

4.7 Effects on ability to drive and use machines

This product has no or negligible influence on the ability to drive and use machines.

4.8 Undesirable effects

Effects of Smoking Cessation
Some symptoms may be related to nicotine withdrawal associated with stopping smoking. These can include: irritability/aggression, frustration/anger, dysphoria/depressed mood, anxiety, restlessness, poor concentration, increased appetite/weight gain, urges to smoke (cravings), night-time awakenings/sleep disturbance, decreased heart rate, dizziness, presyncopal symptoms, cough, constipation, gingival bleeding or nasopharyngitis.
Increased frequency of aphthous ulcer may occur after stopping smoking. The causality is unclear.

Effects of Vaping Cessation
The nicotine withdrawal effects of vaping cessation have not been established; however it is anticipated that many of the effects relating to nicotine withdrawal will be the same as those seen with tobacco smoking cessation.

Adverse Drug Reactions
This product may cause adverse reactions similar to those associated with nicotine given by other means, including smoking and vaping, and these are mainly dose-dependent. At recommended doses this product has not been found to cause any serious adverse effects. Excessive consumption of this product by those who have not been in the habit of inhaling tobacco smoke or vaping could possibly lead to nausea, faintness or headaches.
Most of the undesirable effects reported by the patient occur during the first 3-4 weeks after start of treatment. During the first few days of treatment irritation in the mouth and throat may be experienced. Most patients will get used to this sensation after the first few days.

Allergic reactions (including symptoms of anaphylaxis) can occur during the use of the product.

The adverse reactions observed in patients treated with oral nicotine formulations during clinical trials and post-marketing experience are listed below by system organ class (SOC).
Frequencies are defined in accordance with current guidance as: very common (≥1/10); common (≥1/100, <1/10); uncommon (≥1/1 000, <1/100); rare (≥1/10 000, <1/1 000); very rare (<1/10 000); not known (cannot be estimated from the available data).

Body System	**Reported adverse event (Preferred Term)**	**Incidence**
Immune system disorders	Hypersensitivity[a]	Common
	Anaphylactic reaction[a]	Not known
Psychiatric disorders	Abnormal dreams[*]	Uncommon

Body System	Reported adverse event (Preferred Term)	Incidence
Nervous system disorders	Headache[a#]	Very common
	Burning sensation[c]	Common
	Dizziness	Common
	Dysgeusia	Common
	Paraesthesia[a]	Common
	Seizures	Not known
Eye disorders	Blurred vision	Not known
	Lacrimation increased	Not known
Cardiac disorders	Palpitations[a]	Uncommon
	Tachycardia[a]	Uncommon
	Atrial fibrillation	Very rare
Vascular disorders	Flushing[a]	Uncommon
	Hypertension[a]	Uncommon
Respiratory, thoracic and mediastinal disorders	Cough**	Common
	Sore mouth or throat	Very common
	Throat irritation**	Very common
	Bronchospasm	Uncommon
	Dysphonia	Uncommon
	Dyspnoea[a]	Uncommon
	Nasal congestion	Uncommon
	Sneezing	Uncommon
	Throat tightness	Uncommon
Gastrointestinal disorders	Hiccups****	Very common
	Nausea[a]	Very common
	Abdominal pain	Common
	Diarrhoea***	Common
	Dry mouth	Common
	Dyspepsia	Common
	Flatulence	Common
	Salivary hypersecretion	Common
	Stomatitis	Common
	Vomiting[a]	Common
	Eructation	Uncommon
	Glossitis	Uncommon
	Oral mucosal blistering and exfoliation	Uncommon
	Paraesthesia oral***	Uncommon
	Dysphagia	Rare
	Hypoaesthesia oral***	Rare
	Retching	Rare
	Dry throat	Not known
	Gastrointestinal discomfort[a]	Not known
	Lip pain	Not known
Musculoskeletal and connective tissue disorders	Pain in Jaw[b]	Uncommon
	Muscle tightness[b]	Not known

Body System	Reported adverse event (Preferred Term)	Incidence
Skin and Subcutaneous Tissue Disorders	Hyperhidrosis[a]	Uncommon
	Pruritus[a]	Uncommon
	Rash[a]	Uncommon
	Urticaria[a]	Uncommon
	Erythema[a]	Not known
General disorders and administration site conditions	Fatigue[a]	Common
	Asthenia[a]	Uncommon
	Chest discomfort and pain[a]	Uncommon
	Malaise[a]	Uncommon
	Allergic reactions including angioedema	Rare

[a] Systemic effects;
[b] Tightness of jaw and pain in jaw with nicotine gum formulation
[c] At the application site
*Identified only for formulations applied during the night
**Higher frequency observed in clinical studies with inhaler formulation.
***Reported the same or less frequently than placebo
****Higher frequency observed in clinical studies with mouth spray formulation
[#] Although the frequency in the active group is less than that of the placebo group, the frequency in the specific formulation in which the PT was identified as a systemic ADR was greater in the active group than the placebo group.

Reporting of Suspected Adverse Reactions.
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

4.9 Overdose

Symptoms: Symptoms of overdose with nicotine from this product may occur in smokers/vapers who have previously had a low nicotine intake from cigarettes/e-cigarettes or if other sources of nicotine are used concomitantly with this product.

Acute or chronic toxicity of nicotine in man is highly dependent on mode and route of administration. Adaptation to nicotine (e.g. in smokers/vapers) is known to significantly increase tolerability compared with non-smokers/vapers. The minimum lethal dose of nicotine in a non-tolerant man has been estimated to be 40 to 60 mg. Symptoms of acute nicotine poisoning include nausea, vomiting, increased salivation, abdominal pain, diarrhoea, sweating, headache, dizziness, disturbed hearing and marked weakness. In extreme cases, these symptoms may be followed by hypotension, rapid or weak or irregular pulse, breathing difficulties, prostration, circulatory collapse and terminal convulsions.

Management of an overdose: All nicotine intake should stop immediately and

the patient should be treated symptomatically. Artificial respiration should be instituted if necessary. Activated charcoal reduces the gastro-intestinal absorption of nicotine.

Doses of nicotine that are tolerated by adult smokers/vapers during treatment may produce severe symptoms of poisoning in children and may prove fatal. Suspected nicotine poisoning in a child should be considered a medical emergency and treated immediately.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Drug used in nicotine dependence.
ATC code: N07B A01

Nicotine is an agonist at nicotine receptors in the peripheral and central nervous system and has pronounced CNS and cardiovascular effects.
Abrupt cessation of the use of tobacco-containing products following a prolonged period of daily use results in a characteristic withdrawal syndrome that includes four or more of the following: dysphoria or depressed mood; insomnia; irritability, frustration or anger; anxiety; difficulty concentrating, restlessness or impatience; decreased heart rate; and increased appetite or weight gain. Nicotine craving is an important element in the withdrawal syndrome after smoking/vaping cessation.

Clinical studies have shown that nicotine replacement products can help smokers abstain from use by relieving these withdrawal symptoms.

Increased appetite is a recognised symptom of nicotine withdrawal and post-cessation weight gain is common. Clinical trials have demonstrated that Nicotine Replacement Therapy can help control weight following a quit attempt.

A bioequivalence study for Nicorette Cools 2 mg and 4 mg Lozenges measured relief in urges to smoke (i.e. craving relief) at specified intervals after the start of study drug administration.

Study subjects rated urges to smoke using a scale with 4 ordered categories:
1. No or very light urge to smoke (0-25% of maximum urge conceivable)
2. Noticeable urge to smoke (25%-50% of maximum urge conceivable)
3. Disturbing urge to smoke (50%-75% of maximum urge conceivable)
4. Very strong or extreme urge to smoke (75%-100% of maximum urge conceivable)

The data below presents urges to smoke data obtained for Nicorette Cools 2 mg Lozenge in 94 subjects, before and at 2, 5 and 10 minutes after start of treatment administration.

Table 1: Subjects who rated their urges to smoke either ‘No or very light’ or

stronger (number and percent)

How strong was your urge to smoke?	Before start of administration of study treatment	After 2 minutes	After 5 minutes	After 10 minutes
Category 1 (No or very light urge to smoke)	0 (0%)	14 (17.5%)	36 (45%)	50 (62.5%)
Category 2 – Category 4	80 (100%)	66 (82.5%)	44 (55%)	30 (37.5%)

Table 2: Subjects who experienced any relief in urges to smoke (number and percent)

Any relief in urges to smoke?	Before start of administration of study treatment	After 2 minutes	After 5 minutes	After 10 minutes
Yes	0 (0%)	36 (45%)	68 (85%)	75 (93.75%)
No	80 (100%)	44 (55%)	12 (15%)	5 (6.25%)

5.2 Pharmacokinetic properties

Absorption
A Nicorette Cools 2 mg Lozenge dissolves completely, typically in 10-20 minutes. Assuming complete dissolution in the mouth, most of its nicotine is absorbed through the oral mucosa. This fraction is almost entirely delivered to the systemic circulation. The remaining nicotine released in the mouth is swallowed and undergoes considerable first-pass metabolism in the intestine and liver. As a consequence, only a small part of the total nicotine given with a lozenge reaches the circulation via the intestine.

A maximum nicotine plasma concentration of about 5 ng/mL is achieved after a single-dose of the Nicorette Cools 2 mg Lozenge, and about 8 ng/mL after a single-dose of the Nicorette Cools 4 mg Lozenge. Area under the time vs. plasma concentration curve extrapolated to infinity (AUC_∞) after a single-dose of a Nicorette Cools 2 mg Lozenge is about 16 h*ng/mL, and about 31 h*ng/mL after a single-dose of a Nicorette Cools 4 mg Lozenge.

Distribution
The volume of distribution following intravenous administration of nicotine is about 2 to 3 l/kg.
Plasma protein binding of nicotine is less than 5%. Therefore, changes in nicotine binding from use of concomitant drugs or alterations of plasma proteins by disease states would not be expected to have any significant effects on the nicotine pharmacokinetics.

Biotransformation
The major eliminating organ is the liver, although the kidney and lung also metabolise nicotine. More than 20 metabolites of nicotine have been identified, all of which are believed to be less active than the parent compound.

The primary metabolite of nicotine in plasma, cotinine, has a terminal half-life of 15 to 20 hours and concentrations that exceed nicotine by 10-fold.

Elimination
The average plasma clearance is about 70 l/h and the elimination half-life is approximately 2-3 hours.
The primary urinary metabolites are cotinine (12% of the dose) and trans-3-hydroxy-cotinine (37% of the dose). About 10% of nicotine is excreted unchanged in the urine, but as much as 30% of nicotine may be excreted unchanged with high flow rates and acidification of the urine below pH 5.

Characteristics in specific groups of subjects

Renal Impairment
Progressive severity of renal impairment is associated with decreased total clearance of nicotine. Nicotine clearance was decreased by on average 50% in subjects with severe renal impairment. Raised nicotine levels have been seen in smoking subjects undergoing haemodialysis.

Hepatic Impairment
The pharmacokinetics of nicotine is unaffected in individuals with liver cirrhosis and mild liver impairment (Child-Pugh score 5), and decreased by 40-50% in subjects with moderate liver impairment (Child-Pugh score 7). There is no information available in subjects with a Child-Pugh score > 7.

A minor reduction in total clearance of nicotine has been demonstrated in healthy elderly subjects, however not justifying adjustment of dosage.

5.3 Preclinical safety data

Preclinical data indicate that nicotine is neither mutagenic nor genotoxic. There are no other findings derived from preclinical testing of relevance to the prescriber in determining the safety of the product which have not been considered in other relevant sections of this Summary of Product Characteristics.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

<u>Core</u>
Mannitol (E421)
Xanthan gum (E415)
Winterfresh Flavour
Sodium carbonate anhydrous
Sucralose (E955)
Acesulfame potassium (E950)
Magnesium stearate (E470b)

Coating
Hypromellose (Methocel E3)
Winterfresh Flavour
Titanium dioxide (E171)
Sucralose (E955)
Sepifilm gloss
Acesulfame potassium (E950)
Polysorbate 80
Purified water

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

Polypropylene container with silica gel desiccant ("Flip pack"): 36 months
Cardboard box: 36 months. Use within 3 months after removing the overwrap.

6.4 Special precautions for storage

Polypropylene container: Store the lozenges in the original container in order to protect from moisture.
Cardboard box: Store in the original container in order to protect from moisture.

6.5 Nature and contents of container

Polypropylene container with silica gel desiccant ("Flip pack")

Pack Sizes: 20 (1x20), 80 (4x20) and 160 (8x20) lozenges.

Cardboard box of 40 lozenges. Pack sizes: 40 (1x40), 80 (2x40) or 160 (4x40) lozenges.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal

Any unused product or waste material should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

McNeil Products Limited
1 Station Hill Square
Station Hill
Reading
RG1 1LN
UK

8 MARKETING AUTHORISATION NUMBER(S)

PL 15513/0374

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

27/02/2012

10 DATE OF REVISION OF THE TEXT

9 June 2026

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Nicorette Cools 4 mg Lozenge

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each lozenge contains 4 mg nicotine (as nicotine resinate).

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Compressed lozenge.

An oval, white to off-white lozenge imprinted with a “n” on one side and “4” on the other side.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Nicorette Cools 4 mg Lozenge relieves and/or prevents craving and nicotine withdrawal symptoms in nicotine dependence, such as those arising from the use of tobacco or electronic cigarettes . It is indicated to aid quitting or reduction prior to quitting, to assist those who are unwilling or unable to use such products , and as a safer alternative to smoking tobacco for smokers and those around them.

Nicorette Cools 4 mg Lozenge is indicated in pregnant and lactating women making a quit attempt.

4.2 Posology and method of administration

Adults and children over 12 years of age
The strength of lozenge to be used will depend on the smoking/vaping habits of the individual. In general, if the patient smokes 20 or less cigarettes a day, 2 mg nicotine lozenge is indicated. If more than 20 cigarettes per day are smoked, 4 mg nicotine lozenge will be needed to meet the withdrawal of the high serum nicotine levels from heavy smoking.

Light to moderate vapers (e.g. vape infrequently or use low strength e-liquid) should start with 2 mg nicotine lozenge. If the 2 mg nicotine lozenge does not relieve the urge to vape, 4 mg nicotine lozenge should be used. Heavy vapers (e.g. vape frequently or use high strength e-liquid) should use 4 mg nicotine lozenge.

This product should be used whenever the urge to smoke or vape is felt or to prevent cravings in situations where these are likely to occur.

Patients willing or able to stop smoking/vaping immediately should initially replace all their cigarettes/e-cigarettes with the lozenge and as soon as they are able, reduce the number of lozenges used until they have stopped completely.

Patients aiming to reduce cigarettes/e-cigarettes should use the lozenge, , between smoking/vaping episodes, as needed, to prolong smoke/vape-free intervals and to reduce their use as much as possible.

As soon as they are ready patients should aim to quit smoking/vaping completely.

Most patients require 8 to 12 lozenges per day, not to exceed 15 lozenges.

When making a quit attempt behavioural therapy, advice and support will normally improve the success rate. Those who have quit smoking/vaping but are having difficulty discontinuing with the lozenge are recommended to contact their pharmacist or doctor for advice.

For those using the 4 mg lozenges, switching to the 2 mg lozenges may be helpful when stopping treatment or reducing the number of lozenges used each day.

Method of administration
One lozenge should be placed in the mouth and allowed to dissolve. Periodically, the lozenge should be moved from one side of the mouth to the other, and repeated, until the lozenge is completely dissolved. You should not chew or swallow the lozenge.

4.3 Contraindications

Hypersensitivity to any of components of the lozenge.

Nicorette Cools 4 mg Lozenge is contraindicated in children under the age of 12 years.

4.4 Special warnings and precautions for use

Any risks which may be associated with the use of NRT are substantially outweighed in virtually all circumstances by the well-established dangers of continued smoking. The risks of continued vaping are not yet established.
A risk-benefit assessment should be made by an appropriate healthcare professional for patients with the following conditions:

Underlying cardiovascular disease: In stable cardiovascular disease this product presents a lesser hazard than continuing to smoke. However dependent smokers currently hospitalised as a result of myocardial infarction, unstable or worsening angina including Prinzmetal angina, severe dysrhythmia or cerebrovascular

accident and who are considered to be haemodynamically unstable and/or who have uncontrolled hypertension should be encouraged to stop smoking with non-pharmacological interventions. If this fails, this product may be considered, but as data on safety in this patient group are limited, initiation should only be under medical supervision. The risks of continued vaping are not yet established.

Diabetes Mellitus: Patients with diabetes mellitus should be advised to monitor their blood sugar levels more closely than usual when quitting and NRT is initiated as reductions in nicotine induced catecholamine release can affect carbohydrate metabolism.

Renal and hepatic impairment: Use with caution in patients with moderate to severe hepatic impairment and/or severe renal impairment as the clearance of nicotine or its metabolites may be decreased with the potential for increased adverse effects.

Phaeochromocytoma and uncontrolled hyperthyroidism: Use with caution in patients with uncontrolled hyperthyroidism or phaeochromocytoma as nicotine causes release of catecholamines.

Gastrointestinal disease: Nicotine may exacerbate symptoms in patients suffering from oesophagitis, gastric or peptic ulcers and NRT preparations should be used with caution in these conditions. Ulcerative stomatitis has been reported.

Seizures: Potential risks and benefits of nicotine should be carefully evaluated before use in subjects with a history of epilepsy as cases of convulsions have been reported in association with nicotine.

Danger in children: Doses of nicotine tolerated by adult and adolescent smokers or vapers can produce severe toxicity in children that may be fatal. Products containing nicotine should not be left where they may be misused, handled or ingested by children, see section 4.9 Overdose.

Transferred dependence: Transferred dependence is rare and is both less harmful and easier to break than smoking dependence.

Stopping smoking: Polycyclic aromatic hydrocarbons in tobacco smoke induce the metabolism of drugs metabolised by CYP 1A2 (and possibly by CYP 1A1). When a smoker stops smoking, this may result in slower metabolism and a consequent rise in blood levels of such drugs. This is of potential clinical importance for products with a narrow therapeutic window, e.g. theophylline, clozapine and ropinirole.

Choking hazard: Lozenges can represent a choking hazard, therefore keep out of the reach of children. Use with caution in individuals with aspiration and swallowing problems.

4.5 Interaction with other medicinal products and other forms of interaction

No clinically relevant interactions between nicotine replacement therapy and

other drugs have definitely been established. However nicotine may possibly enhance the haemodynamic effects of adenosine i.e. increase in blood pressure and heart rate and also increase pain response (angina-pectoris type chest pain) provoked by adenosine administration.

4.6 Fertility pregnancy and lactation

Pregnancy
Stopping smoking is the single most effective intervention for improving the health of both the pregnant smoker and her baby, and the earlier abstinence is achieved the better. Ideally smoking cessation during pregnancy should be achieved without NRT. Nicotine passes to the foetus and affects its breathing movements and circulation. The effect on the circulation is dose-dependent.

However, if the mother cannot (or is considered unlikely to) quit without pharmacological support, NRT may be used as the risk to the foetus is lower than that expected with smoking tobacco. Stopping completely is by far the best option but if this is not achievable this product may be used in pregnancy as a safer alternative to smoking. Because of the potential for nicotine-free periods, intermittent dose forms are preferable, but patches may be considered as an alternative if there is significant nausea and/or vomiting. If patches are used they should, if possible, be removed at night when the foetus would not normally be exposed to nicotine.

There is no or limited data regarding the effect of vaping in pregnancy.

Use of NRT by the pregnant smoker/vaper should only be initiated after advice from a health care professional.

Lactation
Nicotine should be avoided during breast-feeding. The relatively small amounts of nicotine found in breast milk during NRT use are less hazardous to the infant than second-hand smoke. Intermittent dose forms would minimize the amount of nicotine in breast milk and permit feeding when levels were at their lowest.

There is no or limited data regarding the effect of vaping in lactating women. Use of NRT by breast feeding smokers/vapers should only be initiated after advice from a health care professional. Women should use the product as soon as possible after breastfeeding.

Fertility
In females tobacco smoking delays time to conception, decreases in-vitro fertilization success rates, and significantly increases the risk of infertility.

In males tobacco smoking reduces sperm production, increases oxidative stress, and DNA damage. Spermatozoa from smokers have reduced fertilizing capacity.

The specific contribution of nicotine to these effects in humans is unknown.

There is no or limited data regarding the effect of vaping on fertility.

4.7 Effects on ability to drive and use machines

This product has no or negligible influence on the ability to drive and use machines.

4.8 Undesirable effects

Effects of Smoking Cessation
Some symptoms may be related to nicotine withdrawal associated with stopping smoking. These can include: irritability/aggression, frustration/anger, dysphoria/depressed mood, anxiety, restlessness, poor concentration, increased appetite/weight gain, urges to smoke (cravings), night-time awakenings/sleep disturbance, decreased heart rate, dizziness, presyncopal symptoms, cough, constipation, gingival bleeding or nasopharyngitis.

Increased frequency of aphthous ulcer may occur after stopping smoking. The causality is unclear.

Effects of Vaping Cessation
The nicotine withdrawal effects of vaping cessation have not been established; however it is anticipated that many of the effects relating to nicotine withdrawal will be the same as those seen with tobacco smoking cessation.

Adverse Drug Reactions
This product may cause adverse reactions similar to those associated with nicotine given by other means, including smoking and vaping, and these are mainly dose-dependent. At recommended doses this product has not been found to cause any serious adverse effects. Excessive consumption of this product by those who have not been in the habit of inhaling tobacco smoke or vaping could possibly lead to nausea, faintness or headaches.

Most of the undesirable effects reported by the patient occur during the first 3-4 weeks after start of treatment. During the first few days of treatment irritation in the mouth and throat may be experienced. Most patients will get used to this sensation after the first few days.

Allergic reactions (including symptoms of anaphylaxis) can occur during the use of the product.

The adverse reactions observed in patients treated with oral nicotine formulations during clinical trials and post-marketing experience are listed below by system organ class (SOC).

Frequencies are defined in accordance with current guidance as: very common (≥1/10); common (≥1/100, <1/10); uncommon (≥1/1 000, <1/100); rare (≥1/10 000, <1/1 000); very rare (<1/10 000); not known (cannot be estimated from the available data).

Body System	Reported adverse event (Preferred Term)	Incidence
Immune system disorders	Hypersensitivity[a]	Common
	Anaphylactic reaction[a]	Not known
Psychiatric disorders	Abnormal dreams[*]	Uncommon
Nervous system disorders	Headache[a#]	Very common
	Burning sensation[c]	Common
	Dizziness	Common
	Dysgeusia	Common
	Paraesthesia[a]	Common
	Seizures	Not known
Eye disorders	Blurred vision	Not known
	Lacrimation increased	Not known
Cardiac disorders	Palpitations[a]	Uncommon
	Tachycardia[a]	Uncommon
	Atrial fibrillation	Very rare
Vascular disorders	Flushing[a]	Uncommon
	Hypertension[a]	Uncommon
Respiratory, thoracic and mediastinal disorders	Cough**	Common
	Sore mouth or throat	Very common
	Throat irritation**	Very common
	Bronchospasm	Uncommon
	Dysphonia	Uncommon
	Dyspnoea[a]	Uncommon
	Nasal congestion	Uncommon
	Sneezing	Uncommon
	Throat tightness	Uncommon
Gastrointestinal disorders	Hiccups****	Very common
	Nausea[a]	Very common
	Abdominal pain	Common
	Diarrhoea***	Common
	Dry mouth	Common
	Dyspepsia	Common
	Flatulence	Common
	Salivary hypersecretion	Common
	Stomatitis	Common
	Vomiting[a]	Common
	Eructation	Uncommon
	Glossitis	Uncommon
	Oral mucosal blistering and exfoliation	Uncommon
	Paraesthesia oral***	Uncommon
	Dysphagia	Rare
	Hypoaesthesia oral***	Rare
	Retching	Rare
	Dry throat	Not known
	Gastrointestinal discomfort[a]	Not known
	Lip pain	Not known

Body System	Reported adverse event (Preferred Term)	Incidence
Musculoskeletal and connective tissue disorders	Pain in Jaw[b]	Uncommon
	Muscle tightness[b]	Not known
Skin and Subcutaneous Tissue Disorders	Hyperhidrosis[a]	Uncommon
	Pruritus[a]	Uncommon
	Rash[a]	Uncommon
	Urticaria**	Uncommon
	Erythema[a]	Not known
General disorders and administration site conditions	Fatigue[a]	Common
	Asthenia[a]	Uncommon
	Chest discomfort and pain[a]	Uncommon
	Malaise[a]	Uncommon
	Allergic reactions including angioedema	Rare

[a] Systemic effects;
[b] Tightness of jaw and pain in jaw with nicotine gum formulation
[c] At the application site*Identified only for formulations applied during the night
**Higher frequency observed in clinical studies with inhaler formulation.
***Reported the same or less frequently than placebo
****Higher frequency observed in clinical studies with mouth spray formulation
[#] Although the frequency in the active group is less than that of the placebo group, the frequency in the specific formulation in which the PT was identified as a systemic ADR was greater in the active group than the placebo group.

Reporting of Suspected Adverse Reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

4.9 Overdose

Symptoms: Symptoms of overdose with nicotine from this product may occur in smokers/vapers who have previously had a low nicotine intake from cigarettes/e-cigarettes or if other sources of nicotine are used concomitantly with this product.

Acute or chronic toxicity of nicotine in man is highly dependent on mode and route of administration. Adaptation to nicotine (e.g. in smokers/vapers) is known to significantly increase tolerability compared with non-smokers/vapers. The minimum lethal dose of nicotine in a non-tolerant man has been estimated to be 40 to 60 mg. Symptoms of acute nicotine poisoning include nausea, vomiting, increased salivation, abdominal pain, diarrhoea, sweating, headache, dizziness, disturbed hearing and marked weakness. In extreme cases, these symptoms may be followed by hypotension, rapid or weak or irregular pulse, breathing difficulties, prostration, circulatory collapse and terminal convulsions.

Management of an overdose: All nicotine intake should stop immediately and the patient should be treated symptomatically. Artificial respiration should be instituted if necessary. Activated charcoal reduces the gastro-intestinal absorption of nicotine.

Doses of nicotine that are tolerated by adult smokers/vapers during treatment may produce severe symptoms of poisoning in children and may prove fatal.

Suspected nicotine poisoning in a child should be considered a medical emergency and treated immediately.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Drug used in nicotine dependence.
ATC code: N07B A01
Nicotine is an agonist at nicotine receptors in the peripheral and central nervous system and has pronounced CNS and cardiovascular effects.

Abrupt cessation of the use of tobacco-containing products following a prolonged period of daily use results in a characteristic withdrawal syndrome that includes four or more of the following: dysphoria or depressed mood; insomnia; irritability, frustration or anger; anxiety; difficulty concentrating, restlessness or impatience; decreased heart rate; and increased appetite or weight gain. Nicotine craving is an important element in the withdrawal syndrome after smoking/vaping cessation.

Clinical studies have shown that nicotine replacement products can help smokers abstain from use by relieving these withdrawal symptoms.

Increased appetite is a recognised symptom of nicotine withdrawal and post-cessation weight gain is common. Clinical trials have demonstrated that Nicotine Replacement Therapy can help control weight following a quit attempt.

A bioequivalence study for Nicorette Cools 2 mg and 4 mg Lozenges measured relief in urges to smoke (i.e. craving relief) at specified intervals after the start of study drug administration.

Study subjects rated urges to smoke using a scale with 4 ordered categories:

1. No or very light urge to smoke (0-25% of maximum urge conceivable)
2. Noticeable urge to smoke (25%-50% of maximum urge conceivable)
3. Disturbing urge to smoke (50%-75% of maximum urge conceivable)
4. Very strong or extreme urge to smoke (75%-100% of maximum urge conceivable)

The data below presents urges to smoke data obtained for Nicorette Cools 4 mg Lozenge in 97 subjects, before and at 2, 5 and 10 minutes after start of

treatment administration.

Table 1: Subjects who rated their urges to smoke either 'No or very light' or stronger (number and percent)

How strong was your urge to smoke?	Before start of administration of study treatment	After 2 minutes	After 5 minutes	After 10 minutes
Category 1 (No or very light urge to smoke)	0 (0%)	20 (23.5%)	43 (50.5%)	57 (68%)
Category 2 – Category 4	80 (100%)	65 (76.5%)	42 (49.5%)	28 (32%)

Table 2: Subjects who experienced any relief in urges to smoke (number and percent)

Any relief in urges to smoke?	Before start of administration of study treatment	After 2 minutes	After 5 minutes	After 10 minutes[a]
Yes	0 (0%)	40 (47%)	70 (85%)	78 (93%)
No	90 (100%)	45 (53%)	15 (15%)	6 (7%)

[a] one observation missing

5.2 Pharmacokinetic properties

Absorption
A Nicorette Cools 4 mg Lozenge dissolves completely, typically in 10-20 minutes. Assuming complete dissolution in the mouth, most of its nicotine is absorbed through the oral mucosa. This fraction is almost entirely delivered to the systemic circulation. The remaining nicotine released in the mouth is swallowed and undergoes considerable first-pass metabolism in the intestine and liver. As a consequence, only a small part of the total nicotine given with a lozenge reaches the circulation via the intestine.

A maximum nicotine plasma concentration of about 5 ng/ml is achieved after a single-dose of the Nicorette Cools 2 mg Lozenge, and about 8 ng/mL after a single-dose of the Nicorette Cools 4 mg Lozenge. Area under the time vs. plasma concentration curve extrapolated to infinity (AUC_∞) after a single-dose of a Nicorette Cools 2 mg Lozenge is about 16 h*ng/ml, and about 31 h*ng/ml after a single-dose of a Nicorette Cools 4 mg Lozenge.

Distribution
The volume of distribution following intravenous administration of nicotine is about 2 to 3 l/kg.
Plasma protein binding of nicotine is less than 5%. Therefore, changes in nicotine binding from use of concomitant drugs or alterations of plasma proteins by disease states would not be expected to have any significant effects on the

nicotine pharmacokinetics.

Biotransformation
The major eliminating organ is the liver, although the kidney and lung also metabolise nicotine. More than 20 metabolites of nicotine have been identified, all of which are believed to be less active than the parent compound.

The primary metabolite of nicotine in plasma, cotinine, has a terminal half-life of 15 to 20 hours and concentrations that exceed nicotine by 10-fold.

Elimination
The average plasma clearance is about 70 l/h and the elimination half-life is approximately 2-3 hours.

The primary urinary metabolites are cotinine (12% of the dose) and trans-3-hydroxy-cotinine (37% of the dose). About 10% of nicotine is excreted unchanged in the urine, but as much as 30% of nicotine may be excreted unchanged with high flow rates and acidification of the urine below pH 5.

Characteristics in specific groups of subjects

Renal Impairment
Progressive severity of renal impairment is associated with decreased total clearance of nicotine. Nicotine clearance was decreased by on average 50% in subjects with severe renal impairment. Raised nicotine levels have been seen in smoking subjects undergoing haemodialysis.

Hepatic Impairment
The pharmacokinetics of nicotine is unaffected in individuals with liver cirrhosis and mild liver impairment (Child-Pugh score 5), and decreased by 40-50% in subjects with moderate liver impairment (Child-Pugh score 7). There is no information available in subjects with a Child-Pugh score > 7.

A minor reduction in total clearance of nicotine has been demonstrated in healthy elderly subjects, however not justifying adjustment of dosage.

5.3 Preclinical safety data

Preclinical data indicate that nicotine is neither mutagenic nor genotoxic. There are no other findings derived from preclinical testing of relevance to the prescriber in determining the safety of the product which have not been considered in other relevant sections of this Summary of Product Characteristics.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

<u>Core</u>
Mannitol (E421)

Xanthan gum (E415)
Winterfresh Flavour
Sodium carbonate anhydrous
Sucralose (E955)
Acesulfame potassium (E950)
Magnesium stearate (E470b)

Coating
Hypromellose (Methocel E3)
Winterfresh Flavour
Titanium dioxide (E171)
Sucralose (E955)
Sepifilm gloss
Acesulfame potassium (E950)
Polysorbate 80
Purified water

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

Polypropylene container with silica gel desiccant ("Flip pack"): 36 months
Cardboard box: 36 months. Use within 3 months after removing the overwrap.

6.4 Special precautions for storage

Polypropylene container: Store the lozenges in the original container in order to protect from moisture.
Cardboard box: Store in the original container in order to protect from moisture.

6.5 Nature and contents of container

Polypropylene container with silica gel desiccant ("Flip pack")
Pack Sizes: 20 (1x20) and 80 (4x20) lozenges.
Cardboard box of 40 lozenges. Pack sizes: 40 (1x40), 80 (2x40) and 160 (4x40) lozenges.
Not all pack sizes may be marketed.

6.6 Special precautions for disposal

Any unused product or waste material should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

McNeil Products Limited
1 Station Hill Square
Station Hill

Reading
RG1 1LN
UK

8 MARKETING AUTHORISATION NUMBER(S)

PL 15513/0375

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

27/02/2012

10 DATE OF REVISION OF THE TEXT

9 June 2026

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Nicorette Fruit 2 mg Lozenge

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each lozenge contains 2 mg nicotine (as nicotine resinate).

Excipients with known effects:
Sulphites (0.000096 mg per lozenge).

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Compressed lozenge.

An oval, white to off-white lozenge imprinted with a “n” on one side and “2” on the other side.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Nicorette Fruit 2 mg Lozenge relieves and/or prevents craving and nicotine withdrawal symptoms in nicotine dependence, such as those arising from the use of tobacco or electronic cigarettes. It is indicated to aid quitting or reduction prior to quitting, to assist those who are unwilling or unable to use such products, and as a safer alternative to smoking tobacco for smokers and those around them.

This product is indicated in pregnant and lactating women making a quit attempt.

4.2 Posology and method of administration

Adults and children over 12 years of age

The strength of lozenge to be used will depend on the smoking/vaping habits of the individual. In general, if the patient smokes 20 or less cigarettes a day, 2 mg nicotine lozenge is indicated. If more than 20 cigarettes per day are smoked, 4 mg nicotine lozenge will be needed to meet the withdrawal of the high serum nicotine levels from heavy smoking.

Light to moderate vapers (e.g. vape infrequently or use low strength e-liquid) should start with 2 mg nicotine lozenge. If the 2 mg nicotine lozenge does not relieve the urge to vape, 4 mg nicotine lozenge should be used. Heavy vapers (e.g. vape frequently or use high strength e-liquid) should use 4 mg nicotine lozenge.

This product should be used whenever the urge to smoke or vape is felt or to prevent cravings in situations where these are likely to occur.

Patients willing or able to stop smoking/vaping immediately should initially replace all their cigarettes/e-cigarettes with the lozenge and as soon as they are able, reduce the number of lozenges used until they have stopped completely.

Patients aiming to reduce cigarettes/e-cigarettes should use the lozenges between smoking/vaping episodes, as needed, to prolong smoke/vape-free intervals and to reduce their use as much as possible.

As soon as they are ready patients should aim to quit smoking/vaping completely.

Most patients require 8 to 12 lozenges per day, not to exceed 15 lozenges.

When making a quit attempt behavioural therapy, advice and support will normally improve the success rate. Those who have quit smoking/vaping but are having difficulty discontinuing with the lozenge are recommended to contact their pharmacist or doctor for advice.

For those using the 4 mg lozenges, switching to the 2 mg lozenges may be helpful when stopping treatment or reducing the number of lozenges used each day.

Method of administration
One lozenge should be placed in the mouth and allowed to dissolve. Periodically, the lozenge should be moved from one side of the mouth to the other, and repeated, until the lozenge is completely dissolved. You should not chew or swallow the lozenge.

4.3 Contraindications

Hypersensitivity to any of components of the lozenge.

This product is contraindicated in children under the age of 12 years.

4.4 Special warnings and precautions for use

Any risks which may be associated with the use of NRT are substantially outweighed in virtually all circumstances by the well-established dangers of continued smoking. The risks of continued vaping are not yet established.

A risk-benefit assessment should be made by an appropriate healthcare professional for patients with the following conditions:

Underlying cardiovascular disease: In stable cardiovascular disease this product presents a lesser hazard than continuing to smoke. However dependent smokers currently hospitalised as a result of myocardial infarction, unstable or worsening angina including Prinzmetal angina, severe dysrhythmia or cerebrovascular accident and who are considered to be haemodynamically unstable and/or who have uncontrolled hypertension should be encouraged to stop smoking with

non-pharmacological interventions. If this fails, this product may be considered, but as data on safety in this patient group are limited, initiation should only be under medical supervision. The risks of continued vaping are not yet established.

Diabetes Mellitus: Patients with diabetes mellitus should be advised to monitor their blood sugar levels more closely than usual when quitting and NRT is initiated as reductions in nicotine induced catecholamine release can affect carbohydrate metabolism.

Renal and hepatic impairment: Use with caution in patients with moderate to severe hepatic impairment and/or severe renal impairment as the clearance of nicotine or its metabolites may be decreased with the potential for increased adverse effects.

Phaeochromocytoma and uncontrolled hyperthyroidism: Use with caution in patients with uncontrolled hyperthyroidism or phaeochromocytoma as nicotine causes release of catecholamines.

Gastrointestinal disease: Nicotine may exacerbate symptoms in patients suffering from oesophagitis, gastric or peptic ulcers and NRT preparations should be used with caution in these conditions. Ulcerative stomatitis has been reported.

Seizures: Potential risks and benefits of nicotine should be carefully evaluated before use in subjects with a history of epilepsy as cases of convulsions have been reported in association with nicotine.

Danger in children: Doses of nicotine tolerated by adult and adolescent smokers or vapers can produce severe toxicity in children that may be fatal. Products containing nicotine should not be left where they may be misused, handled or ingested by children, see section 4.9 Overdose.

Transferred dependence: Transferred dependence is rare and is both less harmful and easier to break than smoking dependence.

Stopping smoking: Polycyclic aromatic hydrocarbons in tobacco smoke induce the metabolism of drugs metabolised by CYP 1A2 (and possibly by CYP 1A1). When a smoker stops smoking, this may result in slower metabolism and a consequent rise in blood levels of such drugs. This is of potential clinical importance for products with a narrow therapeutic window, e.g. theophylline, clozapine and ropinirole.

Choking hazard: Lozenges can represent a choking hazard, therefore keep out of the reach of children. Use with caution in individuals with aspiration and swallowing problems.

Excipients:
This medicine contains less than 1 mmol sodium (23 mg) per lozenge, that is to say essentially ‘sodium-free’. This medicine also contains a small amount of

sulphites, coming from the flavour, which may rarely cause severe hypersensitivity reactions and bronchospasm.

4.5 Interaction with other medicinal products and other forms of interaction

No clinically relevant interactions between nicotine replacement therapy and other drugs have definitely been established. However nicotine may possibly enhance the haemodynamic effects of adenosine i.e. increase in blood pressure and heart rate and also increase pain response (angina-pectoris type chest pain) provoked by adenosine administration.

4.6 Fertility, pregnancy and lactation

Pregnancy

Stopping smoking is the single most effective intervention for improving the health of both the pregnant smoker and her baby, and the earlier abstinence is achieved the better. Ideally smoking cessation during pregnancy should be achieved without NRT. Nicotine passes to the foetus and affects its breathing movements and circulation. The effect on the circulation is dose-dependent. However, if the mother cannot (or is considered unlikely to) quit without pharmacological support, NRT may be used as the risk to the foetus is lower than that expected with smoking tobacco. Stopping completely is by far the best option but if this is not achievable this product may be used in pregnancy as a safer alternative to smoking. Because of the potential for nicotine-free periods, intermittent dose forms are preferable, but patches may be considered as an alternative if there is significant nausea and/or vomiting. If patches are used they should, if possible, be removed at night when the foetus would not normally be exposed to nicotine.

There is no or limited data regarding the effect of vaping in pregnancy.

Use of NRT by the pregnant smoker/vaper should only be initiated after advice from a healthcare professional.

Lactation

Nicotine should be avoided during breast-feeding. The relatively small amounts of nicotine found in breast milk during NRT use are less hazardous to the infant than second-hand smoke. Intermittent dose forms would minimize the amount of nicotine in breast milk and permit feeding when levels were at their lowest.

There is no or limited data regarding the effect of vaping in lactating women.

Use of NRT by breast feeding smokers/vapers should only be initiated after advice from a health care professional. Women should use the product as soon as possible after breastfeeding.

Fertility

In females tobacco smoking delays time to conception, decreases in-vitro fertilization success rates, and significantly increases the risk of infertility.

In males tobacco smoking reduces sperm production, increases oxidative stress, and DNA damage. Spermatozoa from smokers have reduced fertilizing capacity.

The specific contribution of nicotine to these effects in humans is unknown.

There is no or limited data regarding the effect of vaping on fertility.

4.7 Effects on ability to drive and use machines

This product has no or negligible influence on the ability to drive and use machines.

4.8 Undesirable effects

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Some symptoms may be related to nicotine withdrawal associated with stopping smoking. These can include: irritability/aggression, frustration/anger, dysphoria/depressed mood, anxiety, restlessness, poor concentration, increased appetite/weight gain, urges to smoke (cravings), night-time awakenings/sleep disturbance, decreased heart rate, dizziness, presyncopal symptoms, cough, constipation, gingival bleeding or nasopharyngitis.

Increased frequency of aphthous ulcer may occur after stopping smoking. The causality is unclear.

Effects of Vaping Cessation

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Adverse Drug Reactions

This product may cause adverse reactions similar to those associated with nicotine given by other means, including smoking and vaping, and these are mainly dose-dependent. At recommended doses this product has not been found to cause any serious adverse effects. Excessive consumption of this product by those who have not been in the habit of inhaling tobacco smoke or vaping could possibly lead to nausea, faintness or headaches.

Most of the undesirable effects reported by the patient occur during the first 3-4 weeks after start of treatment. During the first few days of treatment irritation in the mouth and throat may be experienced. Most patients will get used to this sensation after the first few days.

Allergic reactions (including symptoms of anaphylaxis) can occur during the use of the product.

The adverse reactions observed in patients treated with oral nicotine formulations during clinical trials and post-marketing experience are listed below by system organ class (SOC). Frequencies are defined in accordance with current guidance as: very common (≥1/10); common (≥1/100, <1/10);

uncommon (≥1/1 000, <1/100); rare (≥1/10 000, <1/1 000); very rare (<1/10 000); not known (cannot be estimated from the available data).

Body System	**Reported adverse event (Preferred Term)**	**Incidence**
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	Burning sensation[c]	Common
	Dizziness	Common
	Dysgeusia	Common
	Paraesthesia[a]	Common
	Seizures	Not known
Eye disorders	Blurred vision	Not known
	Lacrimation increased	Not known
Cardiac disorders	Palpitations[a]	Uncommon
	Tachycardia[a]	Uncommon
	Atrial fibrillation	Very rare
Vascular disorders	Flushing[a]	Uncommon
	Hypertension[a]	Uncommon
Respiratory, thoracic and mediastinal disorders	Cough**	Common
	Sore mouth or throat	Very common
	Throat irritation**	Very common
	Bronchospasm	Uncommon
	Dysphonia	Uncommon
	Dyspnoea[a]	Uncommon
	Nasal congestion	Uncommon
	Sneezing	Uncommon
	Throat tightness	Uncommon
Gastrointestinal disorders	Hiccups****	Very common
	Nausea[a]	Very common
	Abdominal pain	Common
	Diarrhoea***	Common
	Dry mouth	Common
	Dyspepsia	Common
	Flatulence	Common
	Salivary hypersecretion	Common
	Stomatitis	Common
	Vomiting[a]	Common
	Eructation	Uncommon
	Glossitis	Uncommon
	Oral mucosal blistering and exfoliation	Uncommon
	Paraesthesia oral***	Uncommon
	Dysphagia	Rare
	Hypoaesthesia oral***	Rare

	Retching	Rare
	Dry throat	Not known
	Gastrointestinal discomfort[a]	Not known
	Lip pain	Not known
Musculoskeletal and connective tissue disorders	Pain in Jaw[b]	Uncommon
	Muscle tightness[b]	Not known
Skin and subcutaneous tissue disorders	Hyperhidrosis[a]	Uncommon
	Pruritus[a]	Uncommon
	Rash[a]	Uncommon
	Urticaria**	Uncommon
	Erythema[a]	Not known
General disorders and administration site conditions	Fatigue[a]	Common
	Asthenia[a]	Uncommon
	Chest discomfort and pain [a]	Uncommon
	Malaise[a]	Uncommon
	Allergic reactions including angioedema	Rare

[a] Systemic effects; [b] Tightness of jaw and pain in jaw with nicotine gum formulation
[c] At the application site
*Identified only for formulations applied during the night
**Higher frequency observed in clinical studies with inhaler formulation.
***Reported the same or less frequently than placebo
****Higher frequency observed in clinical studies with mouth spray formulation
[#] Although the frequency in the active group is less than that of the placebo group, the frequency in the specific formulation in which the PT was identified as a systemic ADR was greater in the active group than the placebo group.

Reporting of Suspected Adverse Reactions.
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store or search for MHRA Yellow Card in the Google Play or Apple App Store.

4.9 Overdose

Symptoms: Symptoms of overdose with nicotine from this product may occur in smokers/vapers who have previously had a low nicotine intake from cigarettes/e-cigarettes or if other sources of nicotine are used concomitantly with this product.

Acute or chronic toxicity of nicotine in man is highly dependent on mode and route of administration. Adaptation to nicotine (e.g. in smokers/vapers) is known to significantly increase tolerability compared with non-smokers/vapers. The minimum lethal dose of nicotine in a non-tolerant man has been estimated to be 40 to 60 mg. Symptoms of acute nicotine poisoning include nausea, vomiting, increased salivation, abdominal pain, diarrhoea, sweating, headache, dizziness, disturbed hearing and marked weakness. In extreme cases, these

symptoms may be followed by hypotension, rapid or weak or irregular pulse, breathing difficulties, prostration, circulatory collapse and terminal convulsions.

Management of an overdose: All nicotine intake should stop immediately and the patient should be treated symptomatically. Artificial respiration should be instituted if necessary. Activated charcoal reduces the gastro-intestinal absorption of nicotine.

Doses of nicotine that are tolerated by adult smokers/vapers during treatment may produce severe symptoms of poisoning in children and may prove fatal. Suspected nicotine poisoning in a child should be considered a medical emergency and treated immediately.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Drug used in nicotine dependence.
ATC code: N07B A01

Nicotine is an agonist at nicotine receptors in the peripheral and central nervous system and has pronounced CNS and cardiovascular effects.

Abrupt cessation of the use of tobacco-containing products following a prolonged period of daily use results in a characteristic withdrawal syndrome that includes four or more of the following: dysphoria or depressed mood; insomnia; irritability, frustration or anger; anxiety; difficulty concentrating, restlessness or impatience; decreased heart rate; and increased appetite or weight gain. Nicotine craving is an important element in the withdrawal syndrome after smoking/vaping cessation.

Clinical studies have shown that nicotine replacement products can help smokers abstain from use by relieving these withdrawal symptoms.

Increased appetite is a recognised symptom of nicotine withdrawal and post-cessation weight gain is common. Clinical trials have demonstrated that Nicotine Replacement Therapy can help control weight following a quit attempt.

A bioequivalence study for the 2 mg and 4 mg Lozenge measured relief in urges to smoke (i.e. craving relief) at specified intervals after the start of study drug administration.

Study subjects rated urges to smoke using a scale with 4 ordered categories:

1. No or very light urge to smoke (0-25% of maximum urge conceivable)
2. Noticeable urge to smoke (25%-50% of maximum urge conceivable)
3. Disturbing urge to smoke (50%-75% of maximum urge conceivable)
4. Very strong or extreme urge to smoke (75%-100% of maximum urge conceivable)

The data below presents urges to smoke data obtained for the 2 mg Lozenge in 94 subjects, before and at 2, 5 and 10 minutes after start of treatment administration.

Table 1: Subjects who rated their urges to smoke either 'No or very light' or stronger (number and percent)

How strong was your urge to smoke?	Before start of administration of study treatment	After 2 minutes	After 5 minutes	After 10 minutes
Category 1 (No or very light urge to smoke)	0 (0%)	14 (17.5%)	36 (45%)	50 (62.5%)
Category 2 – Category 4	80 (100%)	66 (82.5%)	44 (55%)	30 (37.5%)

Table 2: Subjects who experienced any relief in urges to smoke (number and percent)

Any relief in urges to smoke?	Before start of administration of study treatment	After 2 minutes	After 5 minutes	After 10 minutes
Yes	0 (0%)	36 (45%)	68 (85%)	75 (93.75%)
No	80 (100%)	44 (55%)	12 (15%)	5 (6.25%)

5.2 Pharmacokinetic properties

Absorption

A 2 mg Lozenge dissolves completely, typically in 10-20 minutes. Assuming complete dissolution in the mouth, most of its nicotine is absorbed through the oral mucosa. This fraction is almost entirely delivered to the systemic circulation. The remaining nicotine released in the mouth is swallowed and undergoes considerable first-pass metabolism in the intestine and liver. As a consequence, only a small part of the total nicotine given with a lozenge reaches the circulation via the intestine.

A maximum nicotine plasma concentration of about 5 ng/ml is achieved after a single-dose of the 2 mg Lozenge, and about 8 ng/mL after a single-dose of the 4 mg Lozenge. Area under the time vs. plasma concentration curve extrapolated to infinity (AUC_∞) after a single-dose of a 2 mg Lozenge is about 16 h*ng/ml, and about 31 h*ng/ml after a single-dose of a 4 mg Lozenge.

Distribution

The volume of distribution following intravenous administration of nicotine is about 2 to 3 l/kg.

Plasma protein binding of nicotine is less than 5%. Therefore, changes in nicotine binding from use of concomitant drugs or alterations of plasma proteins

by disease states would not be expected to have any significant effects on the nicotine pharmacokinetics.

Biotransformation
The major eliminating organ is the liver, although the kidney and lung also metabolise nicotine. More than 20 metabolites of nicotine have been identified, all of which are believed to be less active than the parent compound.

The primary metabolite of nicotine in plasma, cotinine, has a terminal half-life of 15 to 20 hours and concentrations that exceed nicotine by 10-fold.

Elimination
The average plasma clearance is about 70 l/h and the elimination half-life is approximately 2-3 hours.

The primary urinary metabolites are cotinine (12% of the dose) and trans-3-hydroxy-cotinine (37% of the dose). About 10% of nicotine is excreted unchanged in the urine, but as much as 30% of nicotine may be excreted unchanged with high flow rates and acidification of the urine below pH 5.

Characteristics in specific groups of subjects
Renal Impairment
Progressive severity of renal impairment is associated with decreased total clearance of nicotine. Nicotine clearance was decreased by on average 50% in subjects with severe renal impairment. Raised nicotine levels have been seen in smoking subjects undergoing haemodialysis.

Hepatic Impairment
The pharmacokinetics of nicotine is unaffected in individuals with liver cirrhosis and mild liver impairment (Child-Pugh score 5), and decreased by 40-50% in subjects with moderate liver impairment (Child-Pugh score 7). There is no information available in subjects with a Child-Pugh score > 7.

A minor reduction in total clearance of nicotine has been demonstrated in healthy elderly subjects, however not justifying adjustment of dosage.

5.3 Preclinical safety data

Preclinical data indicate that nicotine is neither mutagenic nor genotoxic.

There are no other findings derived from preclinical testing of relevance to the prescriber in determining the safety of the product which have not been considered in other relevant sections of this Summary of Product Characteristics.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Core

Mannitol (E421)
Xanthan gum (E415)
Tutti Frutti Flavour Spray dried (contains traces of sulphites, orange oil, orange oil terpenes, isoamyl butyrate, citral, and gum acacia)
Sodium carbonate anhydrous (E500) (i)
Sucralose (E955)
Acesulfame potassium (E950)
Magnesium stearate (E470b)

Coating
Hypromellose (E464)
Tutti Frutti Flavour liquid (contains orange oil, orange oil terpenes, isoamyl butyrate and citral)
Titanium dioxide (E171)
Microcrystalline Cellulose (E460)
Sucralose (E955)
Acesulfame potassium (E950)
Polysorbate 80
Sepifilm Gloss (contains hypromellose (E464), mica-based pearlescent pigments)

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

Polypropylene container with silica gel desiccant ("Flip pack"): 36 months

Cardboard box: 36 months. Use within 3 months after removing the overwrap.

6.4 Special precautions for storage

Polypropylene container: Store the lozenges in the original container in order to protect from moisture.

Cardboard box: Store in the original container in order to protect from moisture.

6.5 Nature and contents of container

Polypropylene container with silica gel desiccant ("Flip pack")
Pack Sizes: 20 (1x20), 80 (4x20) and 160 (8x20) lozenges.

Cardboard box of 40 lozenges. Pack sizes: 40 (1x40), 80 (2x40) or 160 (4x40) lozenges.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal

Any unused product or waste material should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

McNeil Products Limited
1 Station Hill Square
Station Hill
Reading
RG1 1LN
UK

8 MARKETING AUTHORISATION NUMBER(S)

PL 15513/0393

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

04/05/2018

10 DATE OF REVISION OF THE TEXT

23 Jun 2026

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Nicorette Fruit 4 mg Lozenge

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each lozenge contains 4 mg nicotine (as nicotine resinate).

Excipients with known effects:
Sulphites (0.000096 mg per lozenge).

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Compressed lozenge.

An oval, white to off-white lozenge imprinted with a "n" on one side and "4" on the other side.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Nicorette Fruit 4 mg Lozenge relieves and/or prevents craving and nicotine withdrawal symptoms in nicotine dependence, such as those arising from the use of tobacco or electronic cigarettes. It is indicated to aid quitting or reduction prior to quitting, to assist those who are unwilling or unable to use such products, and as a safer alternative to smoking tobacco for smokers and those around them.

This product is indicated in pregnant and lactating women making a quit attempt.

4.2 Posology and method of administration

Adults and children over 12 years of age

The strength of lozenge to be used will depend on the smoking/vaping habits of the individual. In general, if the patient smokes 20 or less cigarettes a day, 2 mg nicotine lozenge is indicated. If more than 20 cigarettes per day are smoked, 4 mg nicotine lozenge will be needed to meet the withdrawal of the high serum nicotine levels from heavy smoking.

Light to moderate vapers (e.g. vape infrequently or use low strength e-liquid) should start with 2 mg nicotine lozenge. If the 2 mg nicotine lozenge does not relieve the urge to vape, 4 mg nicotine lozenge should be used. Heavy vapers

(e.g. vape frequently or use high strength e-liquid) should use 4 mg nicotine lozenge.

This product should be used whenever the urge to smoke or vape is felt or to prevent cravings in situations where these are likely to occur.

Patients willing or able to stop smoking/vaping immediately should initially replace all their cigarettes/e-cigarettes with the lozenge and as soon as they are able, reduce the number of lozenges used until they have stopped completely.

Patients aiming to reduce cigarettes/e-cigarettes should use the lozenges, between smoking/vaping episodes, as needed, to prolong smoke/vape-free intervals and to reduce their use as much as possible.

As soon as they are ready patients should aim to quit smoking/vaping completely.

Most patients require 8 to 12 lozenges per day, not to exceed 15 lozenges.

When making a quit attempt behavioural therapy, advice and support will normally improve the success rate. Those who have quit smoking/vaping but are having difficulty discontinuing with the lozenge are recommended to contact their pharmacist or doctor for advice.

For those using the 4 mg lozenges, switching to the 2 mg lozenges may be helpful when stopping treatment or reducing the number of lozenges used each day.

Method of administration
One lozenge should be placed in the mouth and allowed to dissolve. Periodically, the lozenge should be moved from one side of the mouth to the other, and repeated, until the lozenge is completely dissolved. You should not chew or swallow the lozenge.

4.3 Contraindications

Hypersensitivity to any of components of the lozenge.

This product is contraindicated in children under the age of 12 years.

4.4 Special warnings and precautions for use

Any risks which may be associated with the use of NRT are substantially outweighed in virtually all circumstances by the well-established dangers of continued smoking. The risks of continued vaping are not yet established.

A risk-benefit assessment should be made by an appropriate healthcare professional for patients with the following conditions:

Underlying cardiovascular disease: In stable cardiovascular disease this product presents a lesser hazard than continuing to smoke. However dependent smokers currently hospitalised as a result of myocardial infarction, unstable or worsening

angina including Prinzmetal angina, severe dysrhythmia or cerebrovascular accident and who are considered to be haemodynamically unstable and/or who have uncontrolled hypertension should be encouraged to stop smoking with non-pharmacological interventions. If this fails, this product may be considered, but as data on safety in this patient group are limited, initiation should only be under medical supervision. The risks of continued vaping are not yet established.

Diabetes Mellitus: Patients with diabetes mellitus should be advised to monitor their blood sugar levels more closely than usual when quitting and NRT is initiated as reductions in nicotine induced catecholamine release can affect carbohydrate metabolism.

Renal and hepatic impairment: Use with caution in patients with moderate to severe hepatic impairment and/or severe renal impairment as the clearance of nicotine or its metabolites may be decreased with the potential for increased adverse effects.

Phaeochromocytoma and uncontrolled hyperthyroidism: Use with caution in patients with uncontrolled hyperthyroidism or phaeochromocytoma as nicotine causes release of catecholamines.

Gastrointestinal disease: Nicotine may exacerbate symptoms in patients suffering from oesophagitis, gastric or peptic ulcers and NRT preparations should be used with caution in these conditions. Ulcerative stomatitis has been reported.

Seizures: Potential risks and benefits of nicotine should be carefully evaluated before use in subjects with a history of epilepsy as cases of convulsions have been reported in association with nicotine.

Danger in children: Doses of nicotine tolerated by adult and adolescent smokers or vapers can produce severe toxicity in children that may be fatal. Products containing nicotine should not be left where they may be misused, handled or ingested by children, see section 4.9 Overdose.

Transferred dependence: Transferred dependence is rare and is both less harmful and easier to break than smoking dependence.

Stopping smoking: Polycyclic aromatic hydrocarbons in tobacco smoke induce the metabolism of drugs metabolised by CYP 1A2 (and possibly by CYP 1A1). When a smoker stops smoking, this may result in slower metabolism and a consequent rise in blood levels of such drugs. This is of potential clinical importance for products with a narrow therapeutic window, e.g. theophylline, clozapine and ropinirole.

Choking hazard: Lozenges can represent a choking hazard, therefore keep out of the reach of children. Use with caution in individuals with aspiration and swallowing problems.

Excipients:
This medicine contains less than 1 mmol sodium (23 mg) per lozenge, that is to say essentially 'sodium-free'. This medicine also contains a small amount of sulphites, coming from the flavour, which may rarely cause severe hypersensitivity reactions and bronchospasm.

4.5 Interaction with other medicinal products and other forms of interaction

No clinically relevant interactions between nicotine replacement therapy and other drugs have definitely been established. However nicotine may possibly enhance the haemodynamic effects of adenosine i.e. increase in blood pressure and heart rate and also increase pain response (angina-pectoris type chest pain) provoked by adenosine administration.

4.6 Fertility, pregnancy and lactation

Pregnancy
Stopping smoking is the single most effective intervention for improving the health of both the pregnant smoker and her baby, and the earlier abstinence is achieved the better. Ideally smoking cessation during pregnancy should be achieved without NRT. Nicotine passes to the foetus and affects its breathing movements and circulation. The effect on the circulation is dose-dependent. However, if the mother cannot (or is considered unlikely to) quit without pharmacological support, NRT may be used as the risk to the foetus is lower than that expected with smoking tobacco. Stopping completely is by far the best option but if this is not achievable this product may be used in pregnancy as a safer alternative to smoking. Because of the potential for nicotine-free periods, intermittent dose forms are preferable, but patches may be considered as an alternative if there is significant nausea and/or vomiting. If patches are used they should, if possible, be removed at night when the foetus would not normally be exposed to nicotine.

There is no or limited data regarding the effect of vaping in pregnancy.

Use of NRT by the pregnant smoker/vaper should only be initiated after advice from a health care professional.

Lactation
Nicotine should be avoided during breast-feeding. The relatively small amounts of nicotine found in breast milk during NRT use are less hazardous to the infant than second-hand smoke. Intermittent dose forms would minimize the amount of nicotine in breast milk and permit feeding when levels were at their lowest.

There is no or limited data regarding the effect of vaping in lactating women.

Use of NRT by breast feeding smokers/vapers should only be initiated after advice from a health care professional. Women should use the product as soon as possible after breastfeeding.

Fertility
In females tobacco smoking delays time to conception, decreases in-vitro fertilization success rates, and significantly increases the risk of infertility.

In males tobacco smoking reduces sperm production, increases oxidative stress, and DNA damage. Spermatozoa from smokers have reduced fertilizing capacity.

The specific contribution of nicotine to these effects in humans is unknown.

There is no or limited data regarding the effect of vaping on fertility.

4.7 Effects on ability to drive and use machines

This product has no or negligible influence on the ability to drive and use machines.

4.8 Undesirable effects

Effects of Smoking Cessation

Some symptoms may be related to nicotine withdrawal associated with stopping smoking. These can include: irritability/aggression, frustration/anger, dysphoria/depressed mood, anxiety, restlessness, poor concentration, increased appetite/weight gain, urges to smoke (cravings), night-time awakenings/sleep disturbance, decreased heart rate, dizziness, presyncopal symptoms, cough, constipation, gingival bleeding or nasopharyngitis.

Increased frequency of aphthous ulcer may occur after stopping smoking. The causality is unclear.

Effects of Vaping Cessation

The nicotine withdrawal effects of vaping cessation have not been established, however it is anticipated that many of the effects relating to nicotine withdrawal will be the same as those seen with tobacco smoking cessation.

Adverse Drug Reactions

This product may cause adverse reactions similar to those associated with nicotine given by other means, including smoking and vaping, and these are mainly dose-dependent. At recommended doses this product has not been found to cause any serious adverse effects. Excessive consumption of this product by those who have not been in the habit of inhaling tobacco smoke or vaping could possibly lead to nausea, faintness or headaches.

Most of the undesirable effects reported by the patient occur during the first 3-4 weeks after start of treatment. During the first few days of treatment irritation in the mouth and throat may be experienced. Most patients will get used to this sensation after the first few days.

Allergic reactions (including symptoms of anaphylaxis) can occur during the use of the product.

The adverse reactions observed in patients treated with oral nicotine formulations during clinical trials and post-marketing experience are listed below by system organ class (SOC). Frequencies are defined in accordance with current guidance as: very common (≥1/10); common (≥1/100, <1/10); uncommon (≥1/1 000, <1/100); rare (≥1/10 000, <1/1 000); very rare (<1/10 000); not known (cannot be estimated from the available data).

Body System	Reported adverse event (Preferred Term)	Incidence
Immune system disorders	Hypersensitivity[a]	Common
	Anaphylactic reaction[a]	Not known
Psychiatric disorders	Abnormal dreams*	Uncommon
Nervous system disorders	Headache[a#]	Very common
	Burning sensation[c]	Common
	Dizziness	Common
	Dysgeusia	Common
	Paraesthesia[a]	Common
	Seizures	Not known
Eye disorders	Blurred vision	Not known
	Lacrimation increased	Not known
Cardiac disorders	Palpitations[a]	Uncommon
	Tachycardia[a]	Uncommon
	Atrial fibrillation	Very rare
Vascular disorders	Flushing[a]	Uncommon
	Hypertension[a]	Uncommon
Respiratory, thoracic and mediastinal disorders	Cough**	Common
	Sore mouth or throat	Very common
	Throat irritation**	Very common
	Bronchospasm	Uncommon
	Dysphonia	Uncommon
	Dyspnoea[a]	Uncommon
	Nasal congestion	Uncommon
	Sneezing	Uncommon
	Throat tightness	Uncommon
Gastrointestinal disorders	Hiccups****	Very common
	Nausea[a]	Very common
	Abdominal pain	Common
	Diarrhoea***	Common
	Dry mouth	Common
	Dyspepsia	Common
	Flatulence	Common
	Salivary hypersecretion	Common
	Stomatitis	Common
	Vomiting[a]	Common
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	Oral mucosal blistering and exfoliation	Uncommon
	Paraesthesia oral***	Uncommon
	Dysphagia	Rare
	Hypoaesthesia oral***	Rare
	Retching	Rare
	Dry throat	Not known
	Gastrointestinal discomfort[a]	Not known

	Lip pain	Not known
Musculoskeletal and connective tissue disorders	Pain in Jaw[b]	Uncommon
	Muscle tightness[b]	Not known
Skin and subcutaneous tissue disorders	Hyperhidrosis[a]	Uncommon
	Pruritus[a]	Uncommon
	Rash[a]	Uncommon
	Urticaria**	Uncommon
	Erythema[a]	Not known
General disorders and administration site conditions	Fatigue[a]	Common
	Asthenia[a]	Uncommon
	Chest discomfort and pain [a]	Uncommon
	Malaise[a]	Uncommon
	Allergic reactions including angioedema	Rare

[a] Systemic effects; [b] Tightness of jaw and pain in jaw with nicotine gum formulation
[c] At the application site
*Identified only for formulations applied during the night
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[#] Although the frequency in the active group is less than that of the placebo group, the frequency in the specific formulation in which the PT was identified as a systemic ADR was greater in the active group than the placebo group.

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Symptoms: Symptoms of overdose with nicotine from this product may occur in smokers/vapers who have previously had a low nicotine intake from cigarettes/e-cigarettes or if other sources of nicotine are used concomitantly with this product.

Acute or chronic toxicity of nicotine in man is highly dependent on mode and route of administration. Adaptation to nicotine (e.g. in smokers/vapers) is known to significantly increase tolerability compared with non-smokers/vapers. The minimum lethal dose of nicotine in a non-tolerant man has been estimated to be 40 to 60 mg. Symptoms of acute nicotine poisoning include nausea,

vomiting, increased salivation, abdominal pain, diarrhoea, sweating, headache, dizziness, disturbed hearing and marked weakness. In extreme cases, these symptoms may be followed by hypotension, rapid or weak or irregular pulse, breathing difficulties, prostration, circulatory collapse and terminal convulsions.

Management of an overdose: All nicotine intake should stop immediately and the patient should be treated symptomatically. Artificial respiration should be instituted if necessary. Activated charcoal reduces the gastro-intestinal absorption of nicotine.

Doses of nicotine that are tolerated by adult smokers/vapers during treatment may produce severe symptoms of poisoning in children and may prove fatal. Suspected nicotine poisoning in a child should be considered a medical emergency and treated immediately.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

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Increased appetite is a recognised symptom of nicotine withdrawal and post-cessation weight gain is common. Clinical trials have demonstrated that Nicotine Replacement Therapy can help control weight following a quit attempt.

A bioequivalence study for the 2 mg and 4 mg lozenges measured relief in urges to smoke (i.e. craving relief) at specified intervals after the start of study drug administration.

Study subjects rated urges to smoke using a scale with 4 ordered categories:

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3. Disturbing urge to smoke (50%-75% of maximum urge conceivable)

4. Very strong or extreme urge to smoke (75%-100% of maximum urge conceivable)

The data below presents urges to smoke data obtained for the 4 mg lozenges in 97 subjects, before and at 2, 5 and 10 minutes after start of treatment administration.

Table 1: Subjects who rated their urges to smoke either 'No or very light' or stronger (number and percent)

How strong was your urge to smoke?	Before start of administration of study treatment	After 2 minutes	After 5 minutes	After 10 minutes
Category 1 (No or very light urge to smoke)	0 (0%)	20 (23.5%)	43 (50.5%)	57 (68%)
Category 2 – Category 4	80 (100%)	65 (76.5%)	42 (49.5%)	28 (32%)

Table 2: Subjects who experienced any relief in urges to smoke (number and percent)

Any relief in urges to smoke?	Before start of administration of study treatment	After 2 minutes	After 5 minutes	After 10 minutes[a]
Yes	0 (0%)	40 (47%)	70 (85%)	78 (93%)
No	90 (100%)	45 (53%)	15 (15%)	6 (7%)

[a] one observation missing

5.2 Pharmacokinetic properties

Absorption

A 4 mg lozenge dissolves completely, typically in 10-20 minutes. Assuming complete dissolution in the mouth, most of its nicotine is absorbed through the oral mucosa. This fraction is almost entirely delivered to the systemic circulation. The remaining nicotine released in the mouth is swallowed and undergoes considerable first-pass metabolism in the intestine and liver. As a consequence, only a small part of the total nicotine given with a lozenge reaches the circulation via the intestine.

A maximum nicotine plasma concentration of about 5 ng/ml is achieved after a single-dose of the 2 mg lozenge, and about 8 ng/mL after a single-dose of the 4 mg lozenge. Area under the time vs. plasma concentration curve extrapolated to infinity (AUC_{∞}) after a single-dose of a 2 mg lozenge is about 16 h*ng/ml, and about 31 h*ng/ml after a single-dose of a 4 mg lozenge.

Distribution

The volume of distribution following intravenous administration of nicotine is about 2 to 3 l/kg.

Plasma protein binding of nicotine is less than 5%. Therefore, changes in nicotine binding from use of concomitant drugs or alterations of plasma proteins by disease states would not be expected to have any significant effects on the nicotine pharmacokinetics.

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The primary metabolite of nicotine in plasma, cotinine, has a terminal half-life of 15 to 20 hours and concentrations that exceed nicotine by 10-fold.

Elimination
The average plasma clearance is about 70 l/h and the elimination half-life is approximately 2-3 hours.

The primary urinary metabolites are cotinine (12% of the dose) and trans-3-hydroxy-cotinine (37% of the dose). About 10% of nicotine is excreted unchanged in the urine, but as much as 30% of nicotine may be excreted unchanged with high flow rates and acidification of the urine below pH 5.

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Progressive severity of renal impairment is associated with decreased total clearance of nicotine. Nicotine clearance was decreased by on average 50% in subjects with severe renal impairment. Raised nicotine levels have been seen in smoking subjects undergoing haemodialysis.

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Sodium carbonate anhydrous (E500) (i)
Sucralose (E955)
Acesulfame potassium (E950)
Magnesium stearate (E470b)

Coating
Hypromellose (E464)
Tutti Frutti Flavour liquid (contains orange oil, orange oil terpenes, isoamyl butyrate and citral)
Titanium dioxide (E171)
Sucralose (E955)
Microcrystalline Cellulose (E460)
Acesulfame potassium (E950)
Polysorbate 80
Sepifilm Gloss (contains hypromellose (E464), mica-based pearlescent pigments)

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

Polypropylene container with silica gel desiccant ("Flip pack"): 36 months

Cardboard box: 36 months. Use within 3 months after removing the overwrap.

6.4 Special precautions for storage

Polypropylene container: Store the lozenges in the original container in order to protect from moisture.

Cardboard box: Store in the original container in order to protect from moisture.

6.5 Nature and contents of container

Polypropylene container with silica gel desiccant ("Flip pack")
Pack Sizes: 20 (1x20) and 80 (4x20) lozenges.

Cardboard box of 40 lozenges. Pack sizes: 40 (1x40), 80 (2x40) and 160 (4x40) lozenges.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal

Any unused product or waste material should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

McNeil Products Limited
1 Station Hill Square
Station Hill
Reading
RG1 1LN
UK

8 MARKETING AUTHORISATION NUMBER(S)

PL 15513/0394

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

04/05/2018

10 DATE OF REVISION OF THE TEXT

23 Jun 2026

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Nicorette Microtab 2 mg sublingual tablet or Boots NicAssist 2 mg microtab.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Nicotine ß-cyclodextrin complex 17.4 mg, equivalent to 2 mg nicotine.

Excipient(s) with known effect
ß-cyclodextrin

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Sublingual tablet.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

This product relieves and/or prevents craving and nicotine withdrawal symptoms in nicotine dependence, such as those arising from the use of tobacco or electronic cigarettes. It is indicated to aid quitting or reduction prior to quitting, to assist those who are unwilling or unable to use such products, and as a safer alternative to smoking tobacco for smokers and those around them.

It is also indicated in pregnant and lactating women making a quit attempt.

4.2 Posology and method of administration

Behavioural therapy, advice and support will normally improve the success rate.

Smoking/Vaping Cessation

Adults (over 18 years of age)
The patient should make every effort to stop smoking or vaping completely during treatment with this product.

The initial dose is based on the individual's nicotine dependence. The tablet is used sublingually with a recommended dose of one tablet per hour or, for heavy smokers (smoking more than 20 cigarettes per day)/heavy vapers (e.g. vape frequently or use high strength e-liquid), two tablets per hour. Allow the tablet to dissolve slowly (about 30 minutes). You should not swallow or chew the tablet.

Increasing to two tablets per hour may be considered for patients who fail to stop smoking/vaping with one tablet-per-hour regimen or for those whose nicotine withdrawal symptoms remain so strong as to foresee a relapse.

Most patients require 8 to 12 or 16 to 24 tablets per day, not to exceed 40 tablets. The duration of treatment is individual, but up to three months of treatment is recommended. The nicotine dose should then be gradually reduced, by decreasing the total number of tablets used per day. The treatment should be stopped when the daily consumption is down to one or two tablets.

Adults who use NRT beyond 9 months are recommended to seek additional help and advice from a healthcare professional.

Adolescents (12 to 18 years)
The patient should make every effort to stop smoking or vaping completely during treatment with this product.

The initial dose is based on the individual's nicotine dependence. The tablet is used sublingually with a recommended dose of one tablet per hour or, for heavy smokers (smoking more than 20 cigarettes per day)/ heavy vapers (e.g. vape frequently or use high strength e-liquid), two tablets per hour. Increasing to two tablets per hour may be considered for patients who fail to stop smoking/vaping with the one tablet-per-hour regimen or for those whose nicotine withdrawal symptoms remain so strong as to foresee a relapse.

Most patients require 8 to 12 or 16 to 24 tablets per day, not to exceed 40 tablets. Use for up to 8 weeks to break the habit of smoking/vaping, then gradually reduce the dose over a 4 week period. The treatment should be stopped when the daily consumption is down to one or two tablets. As data are limited in this age group, the recommended duration of treatment is 12 weeks. If longer treatment is required, advice from a healthcare professional should be sought.

Smoking/Vaping Reduction

Adults (over 18 years of age)
Use this product between smoking/vaping episodes to manage the urge to smoke/vape, to prolong smoke/vape-free intervals and with the intention to reduce smoking/vaping as much as possible. If a reduction in number of cigarettes/e-cigarettes per day has not been achieved after 6 weeks, professional advice should be sought.

A quit attempt should be made as soon as the patient feels ready, but not later than 6 months after start of treatment. If a quit attempt cannot be made within 9 months after starting treatment, professional advice should be sought.

When making a quit attempt the smoking/vaping cessation instructions above can be followed.

Adolescents (12 to 18 years)
Where adolescents are motivated to stop smoking/vaping abruptly, smoking/vaping cessation should be recommended. However, smoking/vaping reduction can be considered where adolescents are not ready or able to stop smoking/vaping abruptly. As data are limited in this age group, and the recommended duration of NRT is 12 weeks, adolescents should consult a healthcare professional before starting the "smoking/vaping reduction prior to stopping" regimen.

Use this product between smoking/vaping episodes, as needed to manage the urge to smoke/vape, to prolong smoke/vape-free intervals and to reduce their use as much as possible . If a reduction in number of cigarettes/e-cigarettes per day has not been achieved after 6 weeks, professional advice should be sought.

A quit attempt should be made as soon as the patient feels ready, but not later than 6 months after start of treatment. If a quit attempt cannot be made within 9 months after starting treatment, professional advice should be sought.

When making a quit attempt the smoking/vaping cessation instructions for adolescents (12 to 18 years) given above can be followed.

4.3 Contraindications

Hypersensitivity to any component of the sublingual tablet.

4.4 Special warnings and precautions for use

Any risks that may be associated with NRT are substantially outweighed by the well-established dangers of continued smoking. The risks of continued vaping are not yet established.

A risk-benefit assessment should be made by an appropriate healthcare professional for patients with the following conditions:

Underlying cardiovascular disease: In stable cardiovascular disease this product presents a lesser hazard than continuing to smoke. However dependent smokers currently hospitalised as a result of myocardial infarction, unstable or worsening angina including Prinzmetal angina, severe dysrhythmia or CVA and who are considered to be haemodynamically unstable and/or who have uncontrolled hypertension should be encouraged to stop smoking with non-pharmacological interventions. If this fails, this product may be considered, but as data on safety in this patient group are limited, initiation should only be under medical supervision. The risks of continued vaping are not yet established.

Diabetes mellitus: Patients with diabetes mellitus should be advised to monitor their blood sugar levels more closely than usual when quitting and NRT is initiated as reductions in nicotine induced catecholamine release can affect carbohydrate metabolism.

GI disease: Nicotine may exacerbate symptoms in patients suffering from oesophagitis, gastritis or peptic ulcers and NRT preparations should be used with caution in these conditions. Ulcerative stomatitis has been reported.

Renal or hepatic impairment: This product should be used with caution in patients with moderate to severe hepatic impairment and/or severe renal impairment as the clearance of nicotine or its metabolites may be decreased with the potential for increased adverse effects.

Seizures: Potential risks and benefits of nicotine should be carefully evaluated before use in subjects with a history of epilepsy as cases of convulsions have been reported in association with nicotine.

Danger in children: Doses of nicotine tolerated by adult and adolescent smokers or vapers can produce severe toxicity in children that may be fatal. Products containing nicotine should not be left where they may be misused, handled or ingested by children.

Phaeochromocytoma and uncontrolled hyperthyroidism: As nicotine causes release of catecholamines, this product should be used with caution in patients with uncontrolled hyperthyroidism or phaeochromocytoma.

Transferred dependence: Transferred dependence is rare and is both less harmful and easier to break than smoking dependence.

Stopping smoking: Polycyclic aromatic hydrocarbons in tobacco smoke induce the metabolism of drugs metabolised by CYP 1A2 (and possibly by CYP 1A1). When a smoker stops smoking, this may result in slower metabolism and a consequent rise in blood levels of such drugs. This is of

potential clinical importance for products with a narrow therapeutic window, e.g. theophylline, clozapine and ropinirole.

4.5 Interaction with other medicinal products and other forms of interaction

No clinically relevant interactions between nicotine replacement therapy and other drugs have definitely been established. However nicotine may possibly enhance the haemodynamic effects of adenosine i.e. increase in blood pressure and heart rate and also increase pain response (angina-pectoris type chest pain) provoked by adenosine administration.

4.6 Fertility, pregnancy and lactation

Pregnancy
NRT is not contraindicated in pregnancy. The decision to use NRT should be made on a risk-benefit assessment as early on in the pregnancy as possible with the aim of discontinuing use as soon as possible.

Smoking during pregnancy is associated with risks such as intra-uterine growth retardation, premature birth or stillbirth. Stopping smoking is the single most effective intervention for improving the health of both pregnant smoker and her baby. The earlier abstinence is achieved the better.

Ideally smoking cessation during pregnancy should be achieved without NRT. Nicotine passes to the foetus and affects its breathing movements and circulation. The effect on the circulation is dose-dependent. However for women unable to quit on their own, NRT may be recommended to assist a quit attempt, the risk of using NRT to the foetus is lower than that expected with tobacco smoking, due to lower maximal plasma nicotine concentration and no additional exposure to polycyclic hydrocarbons and carbon monoxide.

Because of the potential for nicotine-free periods, intermittent dose forms are preferable as these usually provide a lower daily dose of nicotine than patches. However, patches may be considered as an alternative if the woman is suffering from nausea during pregnancy. If patches are used they should be removed before going to bed.

There is no or limited data regarding the effect of vaping in pregnancy.

Use of NRT by the pregnant smoker/vaper should only be initiated after advice from a health care professional.

Lactation
Nicotine should be avoided during breast-feeding.
However, NRT is not contraindicated in lactation. Nicotine from smoking and NRT is found in breast milk. However the amount of nicotine the infant is exposed to is relatively small and less hazardous than the second-hand smoke they would otherwise be exposed to.

Using intermittent dose NRT preparations, compared with patches, may minimize the amount of nicotine in the breast milk as the time between administrations of NRT and feeding can be more easily prolonged.

There is no or limited data regarding the effect of vaping in lactating women.

Use of NRT by breast feeding smokers/vapers should only be initiated after advice from a health care professional. Women should use the product as soon as possible after breastfeeding.

Fertility
In females tobacco smoking delays time to conception, decreases in-vitro fertilization success rates, and significantly increases the risk of infertility.

In males tobacco smoking reduces sperm production, increases oxidative stress, and DNA damage. Spermatozoa from smokers have reduced fertilizing capacity.

The specific contribution of nicotine to these effects in humans is unknown.

There is no or limited data regarding the effect of vaping on fertility.

4.7 Effects on ability to drive and use machines

This product has no or negligible influence on the ability to drive and use machines.

4.8 Undesirable effects

Effects of Smoking Cessation
Some symptoms may be related to nicotine withdrawal associated with stopping smoking. These can include irritability/aggression, dysphoria/depressed mood, anxiety, restlessness, poor concentration, increased appetite/weight gain, urges to smoke (cravings), night-time awakenings/sleep disturbance, decreased heart rate, dizziness, presyncopal symptoms, cough, constipation, gingival bleeding or nasopharyngitis.

Increased frequency of aphthous ulcer may occur after abstinence from smoking. The causality is unclear.

Effects of Vaping Cessation
The nicotine withdrawal effects of vaping cessation have not been established; however it is anticipated that many of the effects relating to nicotine withdrawal will be the same as those seen with tobacco smoking cessation.

Adverse Drug Reactions
This product may cause adverse reactions similar to those associated with nicotine given by other means, including smoking and vaping, and these are mainly dose-dependent. At recommended doses this product has not been found to cause any serious adverse effects. Excessive consumption of this product by those who have not been in the habit of inhaling tobacco smoke or vaping could possibly lead to nausea, faintness or headaches.

Most of the undesirable effects associated with this product occur during the first 3-4 weeks after starting treatment. Irritation in the mouth and throat may be experienced, however most subjects adapt to this with ongoing use.

Allergic reactions (including symptoms of anaphylaxis) can occur during the use of the product.

The adverse reactions observed in patients treated with oral nicotine formulations during clinical trials and post-marketing experience are listed below by system organ class (SOC).

Frequencies are defined in accordance with current guidance, as: very common (≥1/10); common (≥1/100, <1/10); uncommon (≥1/1 000, <1/100); rare (≥1/10 000, <1/1 000); very rare (<1/10 000); not known - cannot be estimated from the available data.

System Organ Class	**Reported Adverse Event**	**Incidence**
Infections and Infestations	Rhinitis	Common
Immune System	Hypersensitivity[a]	Common
Disorders	Anaphylactic reaction[a]	Not known
Psychiatric Disorders	Abnormal dreams[*]	Uncommon
Nervous System Disorders	Headache[a#] Burning sensation[c] Dizziness Dysgeusia Paraesthesia[a] Seizures	Very common Common Common Common Common Not known
Eye Disorders	Blurred vision Lacrimation increased	Not known Not known
Cardiac Disorders	Palpitations[a] Tachycardia[a] Atrial fibrillation	Common Uncommon Very rare
Vascular Disorders	Flushing[a] Hypertension[a]	Uncommon Uncommon

Respiratory, Thoracic and Mediastinal Disorders	Throat irritation** Cough** Sore mouth or throat Bronchospasm Dysphonia Dyspnoea[a] Nasal congestion Sneezing Throat tightness	Very common Common Common Uncommon Uncommon Uncommon Uncommon Uncommon Uncommon
Gastrointestinal Disorders	Hiccups**** Nausea[a] Abdominal pain Diarrhoea*** Dry mouth Dyspesia Flatulence Salivary hypersecretion Stomatitis Vomiting[a] Eructation Glossitis Oral mucosal blistering and exfoliation Paraesthesia oral*** Dysphagia Hypoaesthesia oral*** Retching Dry throat Gastrointestinal discomfort[a] Lip pain	Very common Very common Common Common Common Common Common Common Common Common Uncommon Uncommon Uncommon Uncommon Rare Rare Rare Not known Not known Not known
Musculoskeletal and Connective Tissue Disorders	Pain in jaw[b] Muscle tightness[b]	Uncommon Not known
Skin and	Hyperhidrosis[a]	Uncommon
Subcutaneous Tissue Disorders	Pruritus[a] Rash[a] Urticaria[a] Erythema[a]	Uncommon Uncommon Uncommon Not known
General Disorders and Administration Site Conditions	Fatigue[a] Asthenia[a] Chest discomfort and pain[a] Malaise[a] Allergic reactions including angioedema	Common Unommon Uncommon Uncommon Rare

[a] Systemic effects;
[b] Tightness of jaw and pain in jaw with nicotine gum formulation
[c] At the application site

*Identified only for formulations applied during the night
**Higher frequency observed in clinical studies with inhaler formulation.
***Reported the same or less frequently than placebo
**** Higher frequency observed in clinical studies with mouth spray formulation
# Although the frequency in the active group is less than that of the placebo group, the frequency in the specific formulation in which the PT was identified as a systemic ADR was greater in the active group than the placebo group.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

4.9 Overdose

Symptoms: Symptoms of overdose with nicotine from this product may occur in smokers/vapers who have previously had a low nicotine intake from cigarettes/e-cigarettes or if other sources of nicotine are used concomitantly with this product.

Acute or chronic toxicity of nicotine in man is highly dependent on mode and route of administration. Adaptation to nicotine (e.g. in smokers/vapers) is known to significantly increase tolerability compared with non-smokers/vapers. The minimum lethal dose of nicotine in a non-tolerant man has been estimated to be 40 to 60 mg. Symptoms of acute nicotine poisoning include nausea, vomiting, increased salivation, abdominal pain, diarrhoea, sweating, headache, dizziness, disturbed hearing and marked weakness. In extreme cases, these symptoms may be followed by hypotension, rapid or weak or irregular pulse, breathing difficulties, prostration, circulatory collapse and terminal convulsions.

Management of an overdose: All nicotine intake should stop immediately and the patient should be treated symptomatically. Artificial respiration should be instituted if necessary. Activated charcoal reduces the gastro-intestinal absorption of nicotine.

Doses of nicotine that are tolerated by adult smokers/vapers during treatment may produce severe symptoms of poisoning in children and may prove fatal.

Suspected nicotine poisoning in a child should be considered a medical emergency and treated immediately.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Drug used in nicotine dependence.
ATC code: N07B A01

The pharmacological effects of nicotine are well documented. Those resulting from using this product are comparatively small. The response at any one time represents a summation of stimulant and depression actions from direct, reflex and chemical mediator influences on several organs. The principal pharmacological actions are central stimulation and/or depression; transient hyperpnoea; peripheral vasoconstriction (usually associated with a rise in systolic pressure); suppression of appetite and stimulation of peristalsis.

5.2 Pharmacokinetic properties

Most of the absorption of nicotine from this product occurs directly through the buccal mucosa. The absolute bioavailability, after sublingual administration of the tablet, is approximately 50%. The systemic bioavailability of orally administered nicotine is lower due to the amount removed initially by the liver (the first-pass effect). Hence, the high and rapidly rising nicotine concentrations seen after smoking are rarely produced by treatment with this product.

Nicotine from smoking is rapidly absorbed from the lungs into arterial plasma whereas nicotine from sublingual tablets passes more slowly into the venous system.

Steady-state trough nicotine plasma concentrations, achieved after ten hourly doses of one tablet, are in the order of magnitude of 10 ng/ml, which is about 50% of normal smoking levels.

There is a slight deviation from dose-linearity of AUC_{inf} and C_{max} when single doses of one, two and three tablets are given. This deviation may be explained by a larger fraction of the higher doses being swallowed and subject to first-pass elimination.

The therapeutic blood concentrations of nicotine, i.e. the blood levels which relieve craving, are based on the individual's nicotine dependence.

5.3 Preclinical safety data

Preclinical data indicate that nicotine is neither mutagenic nor genotoxic.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Crospovidone
ß-cyclodextrin
Colloidal anhydrous silica
Magnesium stearate

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

Two (2) years.

6.4 Special precautions for storage

Do not store above 25ºC.

6.5 Nature and contents of container

Aluminium foil/PVC-PVDC circular-shaped blister strips (discs) of fifteen (15) tablets assembled in cartons, together with a dispenser. The dispenser is used to remove the tablets from the disc.

Package sizes
30 Tablets (two strips), together with the dispenser.
105 Tablets (seven strips), together with the dispenser.
Or
Al/Al blister strips of 10 sublingual tablets.

Package sizes
Cardboard box of 10, 20, 30, 90, 100, 150 or 210 sublingual tablets with a package insert/booklet.
Not all pack sizes may be marketed.

6.6 Special precautions for disposal

Any unused product or waste material should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

McNeil Products Limited
1 Station Hill Square
Station Hill
Reading
RG1 1LN
UK

8 MARKETING AUTHORISATION NUMBER(S)

PL 15513/0178

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

24/01/2008

10 DATE OF REVISION OF THE TEXT

07 April 2026

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Nicorette Nasal Spray
Boots NicAssist 10 mg/ml Nasal Spray

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Nicotine 10 mg/ml. Each spray of 50 µl delivers 0.5 mg nicotine.

Excipient(s) with known effect
Methyl parahyroxybenzoate
Propyl parahydroxybenzoate

For the full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Nasal Spray, solution.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Nicorette Nasal Spray relieves and/or prevents craving and nicotine withdrawal symptoms in nicotine dependence, such as those arising from the use of tobacco or electronic cigarettes. It is indicated to aid quitting or reduction prior to quitting, to assist those who are unwilling or unable to use such products and as a safer alternative to smoking tobacco for smokers and those around them.

It is also indicated in pregnant and lactating women making a quit attempt.

4.2 Posology and method of administration

The patient should make every effort to stop smoking/vaping completely during treatment with Nicorette Nasal Spray.

Behavioural therapy, advice and support will normally improve the success rate.

This product must only be used with other NRT products under the advice of a healthcare professional.

This product is sprayed into the nostril when the unit is activated. If the eyes are sprayed, rinse thoroughly with water.

Directions for use

1) Remove the protective cap.

2) Prime Nicorette Nasal Spray by placing the nozzle between first and second finger with the thumb on the bottom of the bottle. Press several times firmly and quickly until a fine spray appears (up to 7-8 strokes). **Important**: Point the spray safely away when priming it. Do not prime it near children or pets.
3) Insert the spray tip into one nostril, pointing the top towards the back of the nose. Press firmly and quickly. Give a spray into the other nostril.
4) Put on the protective cap

Smoking/Vaping Cessation

Adults (over 18 years of age)

1. The frequency of use depends on the previous smoking/vaping habit of the individual and the level of their nicotine dependence.
2. On commencing treatment the patient uses the spray to treat craving as required, subject to a limit of one spray to each nostril twice an hour.
3. A 50 µl dose of solution is sprayed into the nostril when the unit is activated. This is described as a "spray" and dosage is described using this term. Each spray delivers 0.5 mg of nicotine, about half of which is absorbed.
4. The daily limit of use is 32 mg of nicotine (64 sprays) which is the equivalent of two sprays to each nostril every hour for 16 hours.
5. The method of use of the spray should be according to the instructions.
6. The 3 month course should take the following pattern:
   a. For 8 weeks the patient uses the spray as required, subject to the maxima described above, to relieve craving.
   b. After this period the patient reduces usage until after 4 more weeks treatment has ended. It is suggested that after 2 weeks into this period usage will have been reduced by a half and usage be zero by the last day. Spraying into a single nostril during this period may be helpful in achieving this.
   c. Treatment should be limited to three months. The patient should understand the aim of decreasing the use of the spray to make a final break with nicotine at the end of the course, and also accept that for the first few days of the course nasal irritation may be unpleasant.

Adults who use NRT beyond 9 months are recommended to seek additional help and advice from a healthcare professional.

Adolescents (12 to 18 years)

The dose and method of use are as for adults however as data are limited in this age group, the recommended treatment duration is 12 weeks. If longer treatment is required, advice from a healthcare professional should be sought.

Smoking/Vaping Reduction

Adults (over 18 years of age)

Use this product between smoking/vaping episodes to manage the urge to smoke/vape, to prolong smoke/vape-free intervals and with the intention to reduce smoking/vaping as much as possible. If a reduction in number of

cigarettes/e-cigarettes per day has not been achieved after 6 weeks, professional advice should be sought.

A quit attempt should be made as soon as the patient feels ready, but not later than 6 months after start of treatment. If a quit attempt cannot be made within 9 months after starting treatment, professional advice should be sought.

When making a quit attempt the smoking/vaping cessation instructions above can be followed.

Adolescents (12 to 18 years)
Where adolescents are motivated to stop smoking/vaping abruptly, smoking/vaping cessation should be recommended. However, smoking/vaping reduction can be considered where adolescents are not ready or able to stop smoking/vaping abruptly. As data are limited in this age group, and the recommended duration of NRT is 12 weeks, adolescents should consult a healthcare professional before starting the "smoking/vaping reduction prior to stopping" regimen.

Use this product between smoking/vaping episodes, as needed to manage the urge to smoke/vape, to prolong smoke/vape-free intervals and to reduce their use as much as possible. If a reduction in number of cigarettes/e-cigarettes per day has not been achieved after 6 weeks, professional advice should be sought.

A quit attempt should be made as soon as the patient feels ready, but not later than 6 months after start of treatment. If a quit attempt cannot be made within 9 months after starting treatment, professional advice should be sought.

When making a quit attempt the smoking/vaping cessation instructions for adolescents (12 to 18 years) given above can be followed.

4.3 Contraindications

Hypersensitivity to any component of the nasal spray.

Nicorette Nasal Spray is contraindicated in children under the age of 12 years.

4.4 Special warnings and precautions for use

Any risks that may be associated with NRT are substantially outweighed by the well-established dangers of continued smoking. The risks of continued vaping are not yet established.

A risk-benefit assessment should be made by an appropriate healthcare professional for patients with the following conditions:

Underlying cardiovascular disease: In stable cardiovascular disease this product presents a lesser hazard than continuing to smoke. However dependent smokers currently hospitalised as a result of myocardial infarction, unstable or worsening angina including Prinzmetal angina, severe dysrhythmia or CVA and who are considered to be haemodynamically unstable and/or who have uncontrolled hypertension should be encouraged to

stop smoking with non-pharmacological interventions. If this fails, this product may be considered, but as data on safety in this patient group are limited, initiation should only be under medical supervision. The risks of continued vaping are not yet established.

Diabetes mellitus: Patients with diabetes mellitus should be advised to monitor their blood sugar levels more closely than usual when quitting and NRT is initiated as reductions in nicotine induced catecholamines release can affect carbohydrate metabolism.

GI disease: Nicotine may exacerbate symptoms in patients suffering from oesophagitis, gastritis or peptic ulcers and NRT preparations should be used with caution in these conditions. Ulcerative stomatitis has been reported.

Renal or hepatic impairment: Nicorette Nasal Spray should be used with caution in patients with moderate to severe hepatic impairment and/or severe renal impairment as the clearance of nicotine or its metabolites may be decreased with the potential for increased adverse effects.

Seizures: Potential risks and benefits of nicotine should be carefully evaluated before use in subjects with a history of epilepsy as cases of convulsions have been reported in association with nicotine.

Danger in children: Doses of nicotine tolerated by adult and adolescent smokers or vapers can produce severe toxicity in children that may be fatal. Products containing nicotine should not be left where they may be misused, handled or ingested by children.

Phaeochromocytoma and uncontrolled hyperthyroidism: As nicotine causes release of catecholamines, this product should be used with caution in patients with uncontrolled hyperthyroidism or phaeochromocytoma.

Transferred dependence: Transferred dependence is rare and is both less harmful and easier to break than smoking dependence.

Stopping smoking: Polycyclic aromatic hydrocarbons in tobacco smoke induce the metabolism of drugs metabolised by CYP 1A2 (and possibly by CYP 1A1). When a smoker stops smoking, this may result in slower metabolism and a consequent rise in blood levels of such drugs. This is of potential clinical importance for products with a narrow therapeutic window, e.g. theophylline, clozapine and ropinirole.

Bronchial asthma: A few cases of exacerbation of bronchospasm in patients with bronchial asthma have been reported. Use of the spray in patients with hyperreactive airways is not recommended.

Excipients: This product contains methyl- and propyl- hydroxybenzoates (E217 and E218); which may cause allergic reactions (possibly delayed) and exceptionally, bronchospasm.

A clinical study confirms the safe use of this product, by smokers with chronic rhinitis and sinusitis.

Care should be taken not to spray the eyes whilst administering the spray.

4.5 Interaction with other medicinal products and other forms of interactions

No clinically relevant interactions between nicotine replacement therapy and other drugs have definitely been established. However nicotine may possibly enhance the haemodynamic effects of adenosine i.e. increase in blood pressure and heart rate and also increase pain response (angina-pectoris type chest pain) provoked by adenosine administration.

4.6 Fertility, pregnancy and lactation

Pregnancy

NRT is not contraindicated in pregnancy. The decision to use NRT should be made on a risk-benefit assessment as early on in the pregnancy as possible with the aim of discontinuing use as soon as possible.

Smoking during pregnancy is associated with risks such as intra-uterine growth retardation, premature birth or stillbirth. Stopping smoking is the single most effective intervention for improving the health of both pregnant smoker and her baby. The earlier abstinence is achieved the better.

Ideally smoking cessation during pregnancy should be achieved without NRT. Nicotine passes to the foetus and affects its breathing movements and circulation. The effect on the circulation is dose-dependent. However for women unable to quit on their own, NRT may be recommended to assist a quit attempt.

However the risk of using NRT to the foetus is lower than that expected with tobacco smoking, due to lower maximal plasma nicotine concentration and no additional exposure to polycyclic hydrocarbons and carbon monoxide.

Because of the potential for nicotine-free periods, intermittent dose forms are preferable as these usually provide a lower daily dose of nicotine than patches. However, patches may be considered if the woman is suffering from nausea during pregnancy. If patches are used they should be removed before going to bed.

There is no or limited data regarding the effect of vaping in pregnancy.

Use of NRT by the pregnant smoker/vaper should only be initiated after advice from a health care professional.

Lactation

Nicotine should be avoided during breast-feeding. However, NRT is not contraindicated in lactation. Nicotine from smoking and NRT is found in breast milk. However the amount of nicotine the infant is exposed to is relatively small and less hazardous than the second-hand smoke they would otherwise be exposed to.

Using intermittent dose NRT preparations, compared with patches, may minimize the amount of nicotine in the breast milk as the time between administrations of NRT and feeding can be more easily prolonged.

There is no or limited data regarding the effect of vaping in lactating women.

Use of NRT by breast feeding smokers/vapers should only be initiated after advice from a health care professional. Women should use the product as soon as possible after breastfeeding.

Fertility
In females tobacco smoking delays time to conception, decreases in-vitro fertilization success rates, and significantly increases the risk of infertility.

In males tobacco smoking reduces sperm production, increases oxidative stress, and DNA damage. Spermatozoa from smokers have reduced fertilizing capacity.

The specific contribution of nicotine to these effects in humans is unknown.

There is no or limited data regarding the effect of vaping on fertility.

4.7 Effects on ability to drive and use machines
The nasal spray should not be used whilst the user is driving or operating machinery as sneezing and watering eyes could contribute to accidents.

4.8 Undesirable effects
Effects of Smoking Cessation
Some symptoms may be related to nicotine withdrawal associated with stopping smoking. These can include irritability/aggression, dysphoria/depressed mood, anxiety, restlessness, poor concentration, increased appetite/weight gain, urges to smoke (cravings), night-time awakenings/sleep disturbance, decreased heart rate, dizziness, presyncopal symptoms, cough, constipation, gingival bleeding or nasopharyngitis.

Increased frequency of aphthous ulcer may occur after abstinence from smoking. The causality is unclear.

Effects of Vaping Cessation
The nicotine withdrawal effects of vaping cessation have not been established; however it is anticipated that many of the effects relating to nicotine withdrawal will be the same as those with tobacco smoking cessation.

Adverse Drug Reactions
This product may cause adverse reactions similar to those associated with nicotine given by other means, including smoking and vaping, and these are mainly dose-dependent. At recommended doses this product has not been found to cause any serious adverse effects. Excessive use of this product by

those who have not been in the habit of inhaling tobacco smoke or vaping could possibly lead to nausea, faintness or headaches.

During the first 2 days of treatment, nasal irritation as sneezing, running nose, watering eyes, cough was reported by nearly all (94%) of the patients. Both the frequency and severity declined with continued use.

Allergic reactions (including symptoms of anaphylaxis) can occur during the use of this product.

The adverse reactions observed in patients treated with nicotine nasal spray formulations during clinical trials and post-marketing experience are listed below by System Organ Class (SOC). Frequencies are defined in accordance with current guidance as: very common (≥1/10); common (≥1/100, <1/10); uncommon (≥1/1 000, < 1/100); rare (≥1/10 000, <1/1 000); very rare (<1/10 000), not known (cannot be estimated from the available data).

System Organ Class	**Reported Adverse Event**	**Incidence**
Immune System Disorders	Hypersensitivity[ac#] Anaphylactic reaction[b]	Uncommon Not known
Psychiatric Disorders	Abnormal dreams[*]	Uncommon
Nervous System Disorders	Headache[a] Dizziness Paraesthesia[a] Seizures	Common Common Common Not known
Eye Disorders	Lacrimation increased	Not known
Cardiac Disorders	Palpitations[a] Atrial fibrillation Tachycardia[a]	Common Very rare Not known
Vascular Disorders	Flushing[a] Hypertension[a]	Uncommon Uncommon
Respiratory, Thoracic and Mediastinal Disorders	Rhinorrhoea Cough[**] Throat irritation** Dyspnoea[a] Epistaxis Nasal discomfort Oropharyngeal discomfort and pain Sneezing	Very common Common Common Common Common Not known Not known Not known
Gastrointestinal Disorders	Nausea[a] Vomiting[a] Gastrointestinal discomfort[a]	Common Common Not known
Skin and Subcutaneous Tissue Disorders	Hyperhidrosis[a] Pruritus[a] Rash[a] Angioedema[a] Erythema[a]	Common Common Common Not known Not known

	Urticaria[a]	Not known
General Disorders and Administration Site Conditions	Chest discomfort and pain[a] Fatigue[ac] Malaise[a] Asthenia[a]	Common Uncommon Uncommon Not known

[a] Systemic effects; [b] Reported the same or less frequently than placebo.
[c] Although the frequency is <1% the PT occurred at a frequency ≥1% in another formulation in which the PT was identified as a systemic ADR
*Identified only for formulations applied during the night
**Higher frequency observed in clinical studies with inhaler formulation.
[#] Although the frequency in the active group is less than that of the placebo group, the frequency in the specific formulation in which the PT was identified as a systemic ADR was greater in the active group than the placebo group.

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

4.9 Overdose

Symptoms: Symptoms of overdose with nicotine from this product may occur in smokers/vapers who have previously had a low nicotine intake from cigarettes/e-cigarettes or if other sources of nicotine are used concomitantly with this product.

Acute or chronic toxicity of nicotine in man is highly dependent on mode and route of administration. Adaptation to nicotine (e.g. in smokers/vapers) is known to significantly increase tolerability compared with non-smokers/vapers. The minimum lethal dose of nicotine in a non-tolerant man has been estimated to be 40 to 60 mg. Symptoms of acute nicotine poisoning include nausea, vomiting, increased salivation, abdominal pain, diarrhoea, sweating, headache, dizziness, disturbed hearing and marked weakness. In extreme cases, these symptoms may be followed by hypotension, rapid or weak or irregular pulse, breathing difficulties, prostration, circulatory collapse and terminal convulsions.

Management of an overdose: All nicotine intake should stop immediately and the patient should be treated symptomatically. Artificial respiration should be instituted if necessary. Activated charcoal reduces the gastro-intestinal absorption of nicotine.

Doses of nicotine that are tolerated by adult smokers/vapers during treatment may produce severe symptoms of poisoning in children and may prove fatal. Suspected nicotine poisoning in a child should be considered a medical emergency and treated immediately.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Drug used in nicotine dependence.
ATC code: N07B A01

Through rapid uptake of nicotine through the nasal membranes Nicorette Nasal Spray provides early relief of nicotine withdrawal symptoms. Clinical studies have shown that the nicotine containing products can help people give up smoking.

5.2 Pharmacokinetic properties

Following administration of one dose Nicorette Nasal Spray approximately 56% of the nicotine enters the systemic circulation.

The volume of distribution following i.v. administration of nicotine is approximately (2 to) 3 l/kg and the half-life ranges from 1 to 2 hours. The major eliminating organ is the liver, and average plasma clearance is about 1.2 l/min; the kidney and lung also metabolise nicotine. More than 20 metabolites of nicotine have been identified, all of which are believed to be less active than the parent compound. The primary metabolite of nicotine in plasma, cotinine, has a half-life of 15 to 20 hours and concentrations that exceed nicotine by 10-fold.

Plasma protein binding of nicotine is <5%. Therefore, changes in nicotine binding from use of concomitant drugs or alterations of plasma proteins by disease states would not be expected to have a significant effect on the nicotine kinetics.

The primary urinary metabolites are cotinine (15% of dose) and trans-3-hydroxycotinine (45% of the dose). Usually about 10% of nicotine is excreted unchanged in the urine. As much as 30% may be excreted in the urine with high urine flow rates and acidification below pH5.

Plasma levels of nicotine obtained with Nicorette Nasal Spray rise rapidly, reaching a maximum level – mean – after approximately 10-15 minutes. The mean peak plasma level of nicotine – after steady –state is achieved – given 1 dose/hour, 2 doses/hour and 3 doses/hour approximately 10, 19 and 28 ng/ml respectively.

After repeated administration of the Nicorette Nasal Spray the AUC was significantly higher during the last dosing interval as compared to the first giving an accumulation ratio of 3.1. No dose-dependency has been shown for the doses 0.5 mg and 1 mg nicotine.

The therapeutic blood concentrations of nicotine, (i.e. the blood levels which relieve craving) are individually based on the patient's nicotine dependence.

5.3 Preclinical safety data

No further information.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Disodium phosphate dodecahydrate
Sodium dihydrogen phosphate dihydrate
Anhydrous citric acid
Sodium chloride
Polysorbate 80
NNS aroma DZ-03226 (B-ionone)
Methyl parahyroxybenzoate
Propyl parahydroxybenzoate
Disodium edetate
Purified water

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

Two years.

6.4 Special precautions for storage

No special temperature conditions.

Should be stored protected from light.

6.5 Nature and contents of container

The solution is filled in a Type III Amber glass container equipped with a spray pump consisting of a polypropylene nosepiece, a polyoxymethylene nozzle and a polypropylene protective cap.

Pack size: 10 ml. Each bottle provides approximately 175 metered sprays / 100 doses.

6.6 Special precautions for disposal and handling

Any unused product or waste material should be disposed of in accordance with local requirements

7 MARKETING AUTHORISATION HOLDER

McNeil Products Limited
1 Station Hill Square
Station Hill
Reading
RG1 1LN
UK

8 MARKETING AUTHORISATION NUMBER(S)

PL 15513/0180

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

01 February 2008

10 DATE OF REVISION OF THE TEXT

02 April 2026