

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 freephone 0808 238 9999.

Nicorette Gum (Nicotine) Prescribing Information

See SmPC for full information

Presentation:

Nicorette 2 mg gum and Nicorette 4 mg gum contain 2 mg and 4 mg of nicotine, respectively, in a chewing gum base. Flavours are available in Original, Icy White, Fruitfusion, and Freshmint.

Uses:

Nicorette Gum products relieve and/or prevent 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. These products are also indicated in pregnant and lactating women making a quit attempt.

Dosage:

Nicorette Gum products should be chewed slowly according to the instructions.

Adults and children over 12 years of age: 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, the 2 mg nicotine gum is indicated. If the patient smokes more than 20 cigarettes a day, the 4 mg gum will be needed to meet the withdrawal of the high serum nicotine levels from heavy smoking. Light to moderate vapers who 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. Meanwhile, heavy vapers who vape frequently or use high strength e-liquid) should use 4 mg nicotine gum. Nicorette Gum products 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 Gum, as needed, between smoking/vaping episodes 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. The maximum daily dose of Nicorette Gum products is 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 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.

Contraindications:

Nicorette Gum products are contraindicated in children under 12 years of age and in individuals with known hypersensitivity to nicotine or any of the excipients in the gum. In addition, Nicotine Original Gum should not be used by individuals with rare hereditary problems of fructose intolerance as this product contains sorbitol.

Precautions:

Any risks that may be associated with NRT use 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, diabetes mellitus, gastrointestinal disease, hepatic or renal impairment, seizures, uncontrolled hyperthyroidism, phaeochromocytoma. Smokers who wear dentures may experience difficulty in chewing. The gum may stick to and may, in rare cases, damage dentures. Stopping smoking may alter the metabolism of certain drugs. Transferred dependence is rare and both less harmful and easier to break than smoking dependence. Nicorette Gum products may enhance the haemodynamic effects of, and pain response to adenosine. Doses of nicotine tolerated by adult and adolescent smokers/vapers can produce severe toxicity in children that may be fatal. Keep out of reach and sight of children and dispose of with care. In addition, Nicorette Gum products contain butylated hydroxytoluene (E321), which may cause local skin reactions such as contact dermatitis, or irritation to the eyes and mucous membranes.

Pregnancy and Lactation:

During pregnancy, nicotine passes to the foetus and affects its breathing movements and circulation. The effect on circulation is dose dependent. Smoking/vaping cessation should be achieved without NRT, however if the mother is unable to quit without pharmacological support, NRT may be recommended to assist a quit attempt only after consulting with a healthcare professional as the risk to the foetus with NRT is lower than that expected with smoking tobacco. Because of the potential for nicotine-free periods, intermittent dose forms are preferable, but patches may be considered as an alternative necessary if there is significant nausea and/or vomiting during pregnancy. Nicotine should be avoided during breastfeeding; however, 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 pregnant and lactating women.

Side effects:

Very common: headache, sore mouth or throat, throat irritation, nausea, hiccups.

Common: hypersensitivity, burning sensation, dizziness, dysgeusia, paraesthesia, cough, abdominal pain, diarrhoea, dry mouth, flatulence, salivary hypersecretion, stomatitis, vomiting, dyspepsia, fatigue.

Uncommon: abnormal dreams, palpitations, tachycardia, flushing, hypertension, bronchospasm, dysphonia, dyspnoea, nasal congestion, sneezing, throat tightness, eructation, glossitis, oral mucosal blistering and exfoliation, paraesthesia oral,

urticaria, hyperhidrosis, pruritus, rash, pain in jaw, asthenia, chest discomfort and pain, malaise.

Rare: dysphagia, hypoaesthesia oral, retching, allergic reactions including angioedema.

Very rare: reversible atrial fibrillation.

Not known: anaphylactic reaction, seizures, blurred vision, lacrimation increased, dry throat, gastrointestinal discomfort, lip pain, erythema, muscle tightness.

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.

NHS cost: Original: 2 mg gum 105's £11.89, 210's £19.34; 4 mg gum 105's £14.55, 210's £23.93. Icy White: 2 mg gum 30's £4.80, 105's £11.89, 210's £19.34; 4 mg gum 105's £14.55. Fruitfusion: 2 mg gum 30's £4.89, 105's £11.89; 4 mg gum 105's £14.55. Freshmint: 2 mg gum 30's £4.80, 105's £11.89, 210's £19.34; 4 mg gum 105's £14.55, 210's £23.93.

Legal category: GSL

PL holder: McNeil Products Ltd, 50 – 100 Holmers Farm Way, High Wycombe, Buckinghamshire, HP12 4EG

PL Number(s): Original 2 mg 15513/0169, 4 mg 15513/0170; Icy White 2 mg 15513/0152, 4 mg 15513/0153; Fruitfusion 2 mg 15513/0136, 4 mg 15513/0137; Freshmint 2 mg 15513/0173, 4 mg 15513/0174.

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