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 QuickMist 1mg/spray Mouthspray (nicotine), Nicorette QuickMist Cool Berry 1mg/spray Mouthspray (nicotine) & Nicorette QuickMist SmartTrack 1mg/spray Mouthspray (nicotine) Prescribing Information

See SmPC for full information

Presentation:

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

Uses:

Nicorette QuickMist relieves and/or prevents cravings and nicotine withdrawal symptoms in nicotine dependence, such as those arising from the use of tobacco or electronic cigarettes. 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 indicated in pregnant and lactating women making a quit attempt.

Dosage:

Adults and children over 12 years of age: The patient should make every effort to stop smoking or vaping completely during treatment with Nicorette QuickMist. One or two sprays used when normally would smoke or vape or if cravings emerge. Maximum dose of 4 sprays per hour, not exceeding 2 sprays per dosing episode, and 64 sprays in any 24-hour period. 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 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.

Contraindications:

Nicorette QuickMist is contraindicated in children under 12 years of age and in individuals with known hypersensitivity to nicotine or any excipients in the mouthspray.

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, renal or hepatic

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impairment, seizures, phaeochromocytoma, uncontrolled hyperthyroidism. Stopping smoking may alter the metabolism of certain drugs. Transferred dependence is rare and both less harmful and easier to break than smoking dependence. The use of Nicorette QuickMist 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. This product delivers 7.1 mg of ethanol, 363 ng of propylene glycol (E1520), and 1 mmol of sodium per spray. Poloxamer 407 is an ingredient of these products, which contains butylated hydroxytoluene (BHT or E321). Presence of small amounts of BHT may cause local skin reactions (e.g. contact dermatitis), or irritation to the eyes and mucous membranes. Keep out of reach and sight of children. Dispose of with care. Do not spray into eyes whilst administering the spray.

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 during pregnancy should be achieved without NRT. However, if the mother cannot (or is considered unlikely to) quit without pharmacological support, NRT may be used only after consulting 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, throat irritation, nausea, hiccups.

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

<u>Uncommon:</u> abnormal dreams, palpitations, tachycardia, flushing, hypertension, bronchospasm, dysphonia, dyspnoea, nasal congestion, sneezing, throat tightness, eructation, glossitis, oral mucosal blistering and exfoliation, paraesthesia oral, dry skin, urticaria, angioedema, hyperhidrosis, pruritus, rash, erythema, pain in jaw, asthenia, chest discomfort and pain, malaise, oropharyngeal pain, rhinorrhoea, gingivitis, musculoskeletal pain, hyperhidrosis.

Rare: dysphagia, hypoaesthesia oral, retching.

<u>Not known:</u> atrial fibrillation, anaphylactic reaction, blurred vision, lacrimation increased, dry throat, gastrointestinal discomfort, lip pain, muscle tightness, angioedema, erythema, seizures.

NHS cost: <u>Nicorette QuickMist 1mg/spray Mouthspray</u>: 1 dispenser pack £14.97, 2 dispenser pack £23.29; <u>Nicorette QuickMist Cool Berry 1mg/spray Mouthspray</u>: 1 dispenser pack £14.97, 2 dispenser pack £23.29; <u>Nicorette QuickMist SmartTrack 1mg/spray Mouthspray</u>: 1 dispenser pack £15.05, 2 pack dispenser £23.92.

Legal category: GSL

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

PL number: Nicorette QuickMist 1mg/spray Mouthspray: 15513/0357, Nicorette QuickMist Cool Berry 1mg/spray Mouthspray: 15513/0395, Nicorette QuickMist SmartTrack 1mg/spray Mouthspray: 15513/0357

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