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 0808 238 9999.

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

See SmPC for full information

Presentation:

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

<u>Adults and Children over 12 years of age:</u> 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:

Children under 12 years of age. Known hypersensitivity to nicotine or any excipients in the mouthspray.

Precautions:

<u>Smokers:</u> Underlying cardiovascular disease. Stopping smoking may alter the metabolism of certain drugs. Transferred dependence is rare and both less harmful and easier to break than smoking dependence.

<u>Smokers or vapers:</u> Diabetes mellitus, GI disease, uncontrolled hyperthyroidism, phaeochromocytoma, hepatic or renal impairment, seizures. May enhance the haemodynamic effects of, and pain response to, adenosine.

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:

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

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, GI discomfort, lip pain, muscle tightness, angioedema, erythema, seizures.

Please refer to Summary of Product Characteristics for detailed information.

RRP (ex VAT): Nicorette QuickMist 1mg/spray Mouthspray: 1 dispenser pack £22.34, 2 dispenser pack £34.76, 6 dispenser pack £100.59; Nicorette QuickMist Cool Berry 1mg/spray Mouthspray: 1 dispenser pack £22.34, 2 dispenser pack £34.76; Nicorette QuickMist SmartTrack 1mg/spray Mouthspray: 1 pack dispenser £22.46, 2 dispenser pack £35.69; Nicorette QuickMist Cool Berry Smart Track 1mg/spray Mouthspray: 2 dispenser pack £33.53.

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; Nicorette QuickMist Cool Berry SmartTrack 1mg/spray Mouthspray: 15513/0395

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