

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

Adverse events should also be reported to McNeil Products Limited on 01344 864 042.

Nicorette QuickMist 1mg/spray mouthspray & Nicorette QuickMist Cool Berry 1mg/spray mouthspray Prescribing Information:

Presentation:

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

Uses:

Relieves and/or prevents craving and nicotine withdrawal symptoms associated with tobacco dependence. It is indicated to aid smokers wishing to quit or reduce prior to quitting, to assist smokers who are unwilling or unable to smoke, and as a safer alternative to smoking 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 completely during treatment with Nicorette QuickMist. One or two sprays to be used when cigarettes normally would have been smoked 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. Up to 4 sprays per hour may be used; 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 is felt or to prevent cravings in situations where these are likely to occur. Smokers willing or able to stop smoking immediately should initially replace all their cigarettes with the Nicorette QuickMist and as soon as they are able, reduce the number of sprays used until they have stopped completely. When making a quit attempt behavioural therapy, advice and support will normally improve the success rate. Smokers aiming to reduce cigarettes should use the Mouthspray, as needed, between smoking episodes to prolong smoke-free intervals and with the intention to reduce smoking as much as possible.

Contraindications:

Children under 12 years of age and hypersensitivity to any of the ingredients.

Precautions:

Underlying cardiovascular disease, diabetes mellitus, G.I disease, uncontrolled hyperthyroidism, phaeochromocytoma, hepatic or renal impairment. Stopping smoking may alter the metabolism of certain drugs. Transferred dependence is rare and both less harmful and easier to break than smoking dependence. May enhance the haemodynamic effects of, and pain response to, adenosine. Keep out of reach and sight of children and dispose of with care. Care should be taken not to spray the eyes whilst administering the spray.

Pregnancy & 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 after consulting a healthcare professional.

Side effects:

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.

Very common: Headache, cough, throat irritation, nausea, hiccups.

Common: Toothache, hypersensitivity, burning sensation, dizziness, dysgeusia, paraesthesia, 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, 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.

Not known: Atrial fibrillation, anaphylactic reaction, blurred vision, lacrimation increased, dry throat, GI discomfort, lip pain, muscle tightness, angioedema, erythema.

NHS Price: Nicorette QuickMist 1mg/spray mouthspray: 1 dispenser pack £13.03, 2 dispenser pack £20.58, Nicorette QuickMist Cool Berry 1mg/spray mouthspray: 1 dispenser pack £13.03, 2 dispenser pack £20.58.

Legal category: GSL

PL holder: McNeil Products Ltd, Roxborough Way, Maidenhead, Berkshire, SL6 3UG

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

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