

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 0800 238 9999.

Nicorette Nasal Spray (nicotine) Prescribing Information

See SmPC for full information

Presentation:

A metered spray bottle containing 10ml of a 10 mg/ml solution of nicotine for intranasal use. Each 50 microlitres delivers 0.5 mg nicotine.

Uses:

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.

Dosage:

The patient should make every effort to stop smoking/vaping completely during treatment with Nicorette Nasal Spray.

Adults (over 18 years): Smoking/vaping cessation: The frequency of use depends on the previous smoking habit of the individual and the level of their nicotine dependence. 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. The daily limit of use is 32 mg of nicotine (or 64 sprays) which is the equivalent of two sprays to each nostril every hour for 16 hours. The use of this product should be restricted to 3 months. For the first 8 weeks, use as required to a maximum of one spray into each nostril twice an hour for 16 hours per day. Then for the next 2 weeks, dosage should be reduced by half. And for the last 2 weeks, usage should be reduced to zero. Adults who use NRT beyond 9 months should seek advice from a healthcare professional. **Smoking/vaping reduction:** Use this nasal spray between smoking/vaping episodes to manage the urge to smoke/vape, to prolong smoke-/vape-free intervals, and to reduce their use as much as possible. A quit attempt should be made as soon as the patient feels ready but no later than 6 months. Professional advice should be sought if no reduction in 6 weeks or no quit attempt in 9 months.

Adolescents (12 to 18 years): Smoking/vaping cessation: The dose and method of use are as for adults; however, as data are limited in this age group, the recommended duration of treatment is 12 weeks. If a longer duration of treatment is required, consult a healthcare professional. **Smoking/vaping reduction:** 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 nasal spray between smoking/vaping episodes to manage the urge to smoke/vape, to prolong smoke-/vape-free intervals, and to reduce their use as much as possible. A quit attempt should be made as soon as the patient feels ready but no later than 6 months. Professional advice should be sought if no reduction in 6 weeks or no quit attempt in 9 months.

Contraindications:

Nicorette Nasal Spray is contraindicated in children under 12 years of age and in individuals with known hypersensitivity to nicotine or any component of the nasal spray.

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 impairment, seizures, pheochromocytoma, uncontrolled hyperthyroidism, bronchial asthma. Stopping smoking may alter the metabolism of certain drugs. Should not be used whilst driving or operating heavy machinery. Transferred dependence is rare and less harmful and easier to break than smoking dependence. Nicorette Nasal Spray 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. This product contains methyl- and propyl-hydroxybenzoates (E217 and E218); which may cause delayed allergic reactions and bronchospasm. Care should be taken not to spray the 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 should be achieved without NRT. However, for women 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: rhinorrhoea.

Common: headache, dizziness, paraesthesia, palpitations, cough, throat irritation, dyspnoea, epistaxis, nausea, vomiting, hyperhidrosis, pruritus, rash, chest discomfort and pain.

Uncommon: hypersensitivity, abnormal dreams, flushing, hypertension, fatigue, malaise.

Very rare: reverse atrial fibrillation.

Not known: anaphylactic reaction, seizures, lacrimation increased, tachycardia, nasal discomfort, oropharyngeal discomfort and pain, sneezing, gastrointestinal discomfort, angioedema, erythema, urticaria, asthenia.

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: £21.05

Legal category: GSL

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

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