

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 Nasal Spray (nicotine) Prescribing Information

Presentation:

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

Uses: Relief of nicotine withdrawal symptoms as an aid to smoking cessation. It is also indicated in pregnant and lactating women.

Dosage: The patient should make every effort to stop smoking completely during treatment with Nicorette Nasal Spray. **Adults (over 18 years):** 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 32mg of nicotine (64 sprays) which is the equivalent of two sprays to each nostril every hour for 16 hours. Use should be restricted to 3 months. For the first 8 weeks as required to a maximum of one spray into each nostril twice an hour for 16 hours per day. For the subsequent 2 weeks, reduce usage by half. Final 2 weeks, reduce usage to zero. Adults who use NRT beyond 9 months should seek advice from a healthcare professional. **Adolescents (12 to 18 years):** As adult dosage, but therapy should not exceed 12 weeks without consulting a healthcare professional.

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

Precautions: Unstable cardiovascular disease, diabetes mellitus, GI disease, renal or hepatic impairment, phaeochromocytoma, 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. May enhance the haemodynamic effects of, and pain response to, adenosine. Keep out of reach and sight of children and dispose of with care. May initially cause nasal irritation. 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, for women unable to quit on their own, NRT may be recommended to assist a quit attempt after consulting a healthcare professional.

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, lacrimation increased, tachycardia, nasal discomfort, oropharyngeal discomfort and pain, sneezing, GI discomfort, angioedema, erythema, urticaria, asthenia.

Please refer to Summary of Product Characteristics for detailed information

NHS Cost: £16.18

Legal category: GSL

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

PL number: 15513/0180

Date of preparation: 26th June 2016