

**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 15 mg Inhalator (nicotine) Prescribing Information**

**See SmPC for full information**

**Presentation:**

Inhalation cartridge containing 15 mg nicotine for oromucosal use via a mouthpiece.

**Uses:**

Nicorette 15 mg Inhalator relieves and/or prevents cravings 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 indicated in pregnant and lactating women making a quit attempt.

**Dosage:**

*Adults and children over 12 years of age:* Nicorette 15 mg Inhalator should be used whenever the urge to smoke/vape is felt or to prevent cravings in situations where these are likely to occur. Smokers/vapers willing or able to stop smoking/vaping immediately should initially replace all their cigarettes/e-cigarettes with the Inhalator and as soon as they are able, reduce the number of cartridges used until they have stopped completely. Smokers aiming to reduce cigarettes/e-cigarettes should use the Inhalator, as needed, between smoking/vaping episodes to prolong smoke-/vape-free intervals and with the intention to reduce smoking/vaping as much as possible. As soon as they are ready smokers/vapers should aim to quit smoking/vaping completely. A maximum of 6 cartridges per day should be used. When making a quit attempt behavioural therapy, advice and support will normally improve the success rate. Those who have quit smoking/vaping but are having difficulty discontinuing their Inhalator are recommended to contact their pharmacist or doctor for advice.

**Contraindications:**

Nicorette 15 mg Inhalator is contraindicated in children under 12 years of age and in individuals with known hypersensitivity to nicotine or any component in the inhalator.

**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, phaeochromocytoma and uncontrolled hyperthyroidism, chronic throat disease, obstructive lung disease, or bronchospastic disease.

Susceptibility to angioedema and urticaria have been reported. 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 15 mg Inhalator 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 contains small parts, which may be potential choking hazards. Keep out of reach and sight of children and dispose of with care.

**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: headache, throat irritation, nausea, stomatitis, hiccups.

Common: hypersensitivity, burning sensation, dizziness, dysgeusia, paraesthesia, cough, nasal congestion, abdominal pain, diarrhoea, dry mouth, dyspepsia, flatulence, salivary hypersecretion, vomiting, fatigue

Uncommon: abnormal dreams, palpitations, tachycardia, flushing, hypertension, bronchospasm, dysphonia, dyspnoea, sneezing, throat tightness, eructation, glossitis, oral mucosal blistering and exfoliation, paraesthesia oral, urticaria, hyperhidrosis, pruritus, rash, urticaria, pain in jaw, asthenia, chest discomfort and pain, malaise.

Rare: dysphagia, hypoaesthesia oral, retching.

Very rare: reversible atrial fibrillation.

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

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:** 4-cartridge pack: £6.43, 20-cartridge pack: £22.64, 36-cartridge pack: £35.66

**Legal category:** GSL

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

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