

**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 Cools 2 mg Lozenge (nicotine), Nicorette Cools 4 mg Lozenge (nicotine), Nicorette Fruit 2 mg Lozenge (nicotine) Prescribing Information**

**See SmPC for full information.**

### **Presentation:**

Nicorette Cools 2 mg Lozenge, Nicorette Fruit 2 mg Lozenge, Nicorette Cools 4 mg Lozenge are oval, white to off-white compressed lozenges containing 2 mg and 4 mg nicotine respectively (as nicotine resinate). All lozenges are imprinted with a “n” on one side. Nicorette Cools 2 mg and Fruit 2 mg have “2” on the other side, while Nicorette Cools 4 mg Lozenge has “4” on the other side.

### **Uses:**

Nicorette Lozenges relieve and/or prevent craving and nicotine withdrawal symptoms in nicotine dependency, such as those arising from the use of tobacco or electronic cigarettes. It is indicated to aid quitting and 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 making a quit attempt.

### **Dosage:**

*Adults and children over 12 years of age:* The strength of lozenge to be used will depend on the smoking/vaping habits of the individual. If the patient smokes 20 or fewer cigarettes a day, 2 mg nicotine lozenge is indicated. If more than 20 cigarettes per day are smoked, 4 mg nicotine lozenge should be used. Light to moderate vapers who vape infrequently or use low strength e-liquid should start with 2 mg nicotine lozenge. If the 2 mg nicotine lozenge does not relieve the urge to vape, 4 mg nicotine lozenge should be used. Heavy vapers who vape frequently or use high strength e-liquid should use 4 mg nicotine lozenge. Nicorette Lozenges should be used whenever the urge to smoke/vape is felt or to prevent cravings in situations where these are likely to occur. Patients willing or able to stop smoking/vaping immediately should initially replace all their cigarettes/e-cigarettes with the lozenge and as soon as they are able, reduce the number of lozenges used until they have stopped completely. Smokers aiming to reduce cigarettes/e-cigarettes should take the lozenge, as needed, between smoking/vaping episodes to prolong smoke-/vape-free intervals and with the intention to reduce their use as much as possible. As soon as they are ready patients should aim to quit smoking/vaping completely. Most smokers require 8 to 12 lozenges per day, not to exceed 15 lozenges. 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 with the lozenge are recommended to contact their pharmacist or doctor for advice. For those using the 4 mg lozenges, switching to the 2 mg lozenges may be helpful when stopping treatment or reducing the number of lozenges used each day.

**Contraindications:**

Nicorette Lozenge products are contraindicated in children under the age of 12 years and in individuals with known hypersensitivity to nicotine or any excipients in the lozenge.

**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, hepatic or renal impairment, seizures, uncontrolled hyperthyroidism, pheochromocytoma, gastrointestinal 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. Nicorette Lozenges 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. Lozenges can represent a choking hazard. Use with caution in individuals with aspiration and swallowing problems. The Tutti Frutti Flavour of Nicorette Fruit Lozenge contains traces of sulphites which may rarely cause severe hypersensitivity reactions and bronchospasm.

**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 cessation should be achieved without NRT, however if the mother is 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. If patches are used as they should, if possible, these should be removed at night when the foetus would not normally be exposed to nicotine. 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, sore mouth or throat, throat irritation, hiccups, nausea.

Common: hypersensitivity, burning sensation, dizziness, dysgeusia, paraesthesia, cough, abdominal pain, diarrhoea, dry mouth, dyspepsia, flatulence, salivary hypersecretion, stomatitis, vomiting, 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, pain in jaw, hyperhidrosis, pruritus, rash, urticaria, asthenia, chest discomfort and pain, malaise.

Rare: dysphagia, hyposensitivity oral, retching, allergic reactions including

angioedema.

Very rare: reversible atrial fibrillation.

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

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:** Nicorette Cools 2 mg Lozenge: 40's (1x40) pack £6.70, 80's (2x40) pack £12.05, 160's (4x40) pack £22.75; Nicorette Fruit 2 mg Lozenge: 40's (1x40) pack £6.70, 80 (2x40) pack £12.05, 160's (4x40) pack £22.75; Nicorette Cools 4 mg Lozenge: 80's (2x40) pack £12.17.

**Legal category:** GSL

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

**PL number:** Nicorette Cools 2 mg Lozenge:15513/0374, Nicorette Fruit 2 mg Lozenge: 15513/0393, Nicorette Cools 4 mg Lozenge: 15513/0375

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