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

## See SmPC for full information.

#### Presentation:

Nicorette Cools 2mg Lozenge, Nicorette Fruit 2mg Lozenge, Nicorette Cools 4mg Lozenge contain 2 mg and 4 mg nicotine respectively (as nicotine resinate).

#### 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 strength of lozenge to be used will depend on the smoking 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. Nicorette Lozenges 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 lozenge and as soon as they are able, reduce the number of lozenges used until they have stopped completely. Smokers aiming to reduce cigarettes should take the lozenge, as needed, between smoking episodes to prolong smoke-free intervals and with the intention to reduce smoking as much as possible. As soon as they are ready smokers should aim to quit smoking 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 but are having difficulty discontinuing with the lozenge are recommended to contact their pharmacist or doctor for advice.

#### Contraindications:

Children under the age of 12 years. Known Hypersensitivity to nicotine or any excipients in the lozenge.

### **Precautions:**

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Underlying cardiovascular disease, diabetes mellitus, hepatic or renal impairment, seizures, uncontrolled hyperthyroidism, phaeochromocytoma, G.I disease, keep out of reach and sight of children. Stopping smoking may alter the metabolism of certain drugs. Lozenges can represent a choking hazard, therefore keep out of the reach of children. Use with caution in individuals with aspiration and swallowing problems. 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. Tutti Frutti Flavour contains traces of sulphites which may rarely cause severe hypersensitivity reactions and bronchospasm. Dispose of with care.

# **Pregnancy and lactation:**

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.

#### Side effects:

<u>Very common:</u> headache, sore mouth or throat, throat irritation, nausea, hiccups. <u>Common:</u> hypersensitivity, cough, burning sensation, dizziness, dysgeusia, paraesthesia, abdominal pain, diarrhoea, dry mouth, flatulence, salivary hypersecretion, stomatitis, vomiting, dyspepsia, fatigue.

<u>Uncommon:</u> abnormal dreams, palpitations, tachycardia, flushing, hypertension, bronchospasm, dysphonia, dyspnoea, nasal congestion, sneezing, throat tightness, eructation, glossitis, oral mucosal blistering and exfoliation, paraesthesia oral, urticaria, hyperhidrosis, pruritus, rash, pain in jaw, asthenia, chest discomfort and pain, malaise. <u>Rare:</u> dysphagia, hypoaesthesia oral, retching, allergic reactions including angioedema. <u>Very rare:</u> reversible atrial fibrillation.

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

Please refer to Summary of Product Characteristics for detailed information.

**NHS Price:** Nicorette Cools 2mg Lozenge: 20 (1x20) pack £3.34, 80 (4x20) pack £12.05, 40 (1x40) pack £6.70, 80 (2x40) pack £12.05, 160 (4x40) pack £22.75. Nicorette Fruit 2mg Lozenge: 80 (4x20) pack £12.05, 40 (1x40) pack £6.70, 80 (2x40) pack £12.05, 160 (4x40) pack £22.75. Nicorette Cools 4mg Lozenge: 80 (4x20) pack £12.17, 80 (2x40) pack £12.17.

Legal category: GSL

**PL holder:** McNeil Products Ltd, 50-100 Holmers Farm Way, High Wycombe, HP12 4EG **PL number:** Nicorette Cools 2mg Lozenge:15513/0374, Nicorette Fruit 2mg Lozenge:

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