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 Microtab 2mg Sublingual Tablet (nicotine B-cyclodextrin) Prescribing Information

# See SmPC for full information Presentation:

Microtab for sublingual use consisting of nicotine B-cyclodextrin complex 17.4 mg, equivalent to 2 mg nicotine.

### Uses:

Relief of nicotine withdrawal symptoms as an aid to smoking cessation. It is used to help smokers ready to stop smoking immediately and also smokers who need to cut down their cigarette use before stopping. It is also indicated in pregnant and lactating women.

#### Dosage:

Adults (over 18 years): The tablet is used sublingually with a recommended dose of one tablet per hour or, for heavy smokers (more than 20 cigarettes per day), two tablets per hour. Most smokers require 8-12 or 16-24 tablets per day, not to exceed 40 tablets. Smoking cessation: Patients should stop smoking during treatment. Duration of treatment is individual but up to 3 months of treatment is recommended. The nicotine dose should then be gradually reduced by decreasing the total number of tablets used per day. Treatment should be stopped when daily consumption is down to one or two tablets. Those who use NRT beyond 9 months should consult a healthcare professional. Smoking reduction: Use the microtab between smoking episodes to reduce smoking. A quit attempt should be made as soon as the smoker feels ready but no later than 6 months. Professional advice should be sought if no reduction in 6 weeks or no guit attempt in 9 months. Adolescents (12 to 18 years): No more than 40 tablets should be used each day. Smoking cessation: As adult dosage, but treatment should be used for up to 8 weeks before gradually reducing over 4 weeks. Treatment should be stopped when daily consumption is down to one or two tablets. If further treatment is required, consult a healthcare professional. Smoking reduction: Only after consulting a healthcare professional.

### **Contraindications:**

Children under the age of 12 years. Hypersensitivity to nicotine or any component in the sublingual tablet.

### **Precautions:**

Underlying cardiovascular disease, diabetes mellitus, GI disease, renal or hepatic impairment, seizures, phaeochromocytoma, uncontrolled hyperthyroidism. Stopping smoking may alter the metabolism of certain drugs. 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.

## **Pregnancy & lactation:**

Smoking cessation during pregnancy 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.

#### Side effects:

Very common: headache, throat irritation, hiccups, nausea.

<u>Common</u>: rhinitis, cough, hypersensitivity, burning sensation, dizziness, dysgeusia, paraesthesia, palpitations, sore mouth and throat, abdominal pain, diarrhea, dry mouth, dyspepsia, flatulence, salivary hypersecretion, stomatitis, vomiting, fatigue.

<u>Uncommon</u>: abnormal dreams, tachycardia, flushing, hypertension, bronchospasm, dysphonia, dyspnea, 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.

<u>*Rare:*</u> dysphagia, hypoaesthesia oral, retching, allergic reactions including angioedema.

Very Rare: reversible atrial fibrillation.

<u>Not known</u>: anaphylactic reaction, seizures, blurred vision, lacrimination increase, dry throat, gastrointestinal discomfort, lip pain, muscle tightness, erythema.

NHS price: 100 pack: £19.14

### Legal category: GSL

**PL holder:** McNeil Products Ltd, 50-100 Holmers Farm Way, High Wycombe, HP12 4EG **PL number:** 15513/0178

Date of prep:19 Aug 21