

**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 2 mg Sublingual Tablet (nicotine $\beta$ -cyclodextrin) Prescribing Information**

**See SmPC for full information**

### **Presentation:**

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

### **Uses:**

Nicorette Microtab 2 mg sublingual tablet relieves and/or prevents craving 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 also indicated in pregnant and lactating women making a quit attempt.

### **Dosage:**

**Adults (over 18 years):** The tablet is used sublingually with a recommended dose of one tablet per hour or, for heavy smokers who smoke more than 20 cigarettes per day, or heavy vapers vaping frequently or using high strength e-liquid, two tablets per hour. Most patients require 8 to 12 or 16 to 24 tablets per day, not to exceed 40 tablets. ***Smoking/vaping cessation:*** Patients should stop smoking/vaping 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. Adults who use NRT beyond 9 months should consult a healthcare professional. ***Smoking/vaping reduction:*** Use the microtab between smoking/vaping episodes to manage the urge to smoke/vape, to prolong smoke-/vape-free intervals, and to reduce their use as much as possible. A quit attempt should be made as soon as the patient feels ready but no later than 6 months. Professional advice should be sought if no reduction in 6 weeks or no quit attempt in 9 months.

**Adolescents (12 to 18 years):** No more than 40 tablets should be used each day. ***Smoking/vaping 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. As data are limited in this age group, the recommended duration of treatment is 12 weeks. If further treatment is required, consult a healthcare professional. ***Smoking/vaping reduction:*** As data are limited in this age group, adolescents should consult a healthcare professional first before starting the *smoking/vaping reduction prior to stopping* regimen. Use the microtab between smoking/vaping episodes to manage the urge to smoke/vape, to prolong smoke-/vape-free intervals, and to reduce their use as much as possible. A quit attempt should be made as soon as the patient feels ready but no later than 6

months. Professional advice should be sought if no reduction in 6 weeks or no quit attempt in 9 months.

**Contraindications:**

Nicorette Microtab 2 mg sublingual tablet is contraindicated in children under 12 years of age and in individuals with known hypersensitivity to nicotine or any component in the sublingual tablet.

**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, pheochromocytoma, 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. Nicorette Microtab 2 mg sublingual tablet 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.

**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 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 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, hiccups, nausea.

Common: rhinitis, hypersensitivity, burning sensation, dizziness, dysgeusia, paraesthesia, palpitations, cough, sore mouth or throat, abdominal pain, diarrhoea, dry mouth, dyspepsia, flatulence, salivary hypersecretion, stomatitis, vomiting, fatigue.

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

Rare: paraesthesia oral, dysphagia, hypoaesthesia oral, allergic reactions including angioedema.

Very rare: reversible atrial fibrillation.

Not known: anaphylactic reaction, seizures, blurred vision, lacrimation increased, retching, 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:** 100 pack: £19.14

**Legal category:** GSL

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