

**Adverse events should be reported. Reporting forms and information can be found at [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard)**

**Adverse events should also be reported to McNeil Products Limited on 01344 864 042.**

## **Nicorette Inhalator (nicotine) Prescribing Information**

### **Presentation:**

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

### **Uses:**

Relieves and/or prevents cravings 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:**

Nicorette Inhalator 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 Inhalator and as soon as they are able, reduce the number of cartridges used until they have stopped completely. Smokers aiming to reduce cigarettes should use the Inhalator, 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. 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, but are having difficulty discontinuing their Inhalator are recommended to contact their pharmacist or doctor for advice.

### **Contraindications:**

Children under 12 years and Hypersensitivity.

### **Precautions:**

Underlying cardiovascular disease, diabetes mellitus, G.I disease, uncontrolled hyperthyroidism, phaeochromocytoma, hepatic or renal impairment, chronic throat disease, obstructive lung disease or bronchospastic 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. May enhance the haemodynamic effects of, and pain response to, adenosine. Keep out of reach and sight of children and dispose of with care. Best used at room temperature.

### **Pregnancy & lactation:**

Smoking cessation during pregnancy should be achieved without NRT. However, for women unable to quit on their own, NRT may be recommended to assist a quit attempt after consulting a healthcare professional.

### **Side effects:**

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

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

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, pain in jaw, asthenia, chest discomfort and pain, malaise, chest discomfort and pain.

Rare: dysphagia, hypoaesthesia oral, retching.

Very rare: reversible atrial fibrillation.

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

*Please refer to Summary of Product Characteristics for detailed information*

**NHS cost:** 4-cartridge pack: £4.87, 20-cartridge pack: £17.78, 36-cartridge pack: £28.28

**Legal category:** GSL

**PL holder:** McNeil Products Ltd, Roxborough Way, Maidenhead, Berkshire, SL6 3UG.

**PL number:** 15513/0358

**Date of preparation:** 27<sup>th</sup> June 2016