

Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard

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

Nicorette Gum (Nicotine) Prescribing Information

Presentation:

Nicorette 2mg gum, Nicorette 4mg gum, and Nicorette 6mg gum contain 2mg, 4mg and 6mg of nicotine respectively, in a chewing gum base. Original, Icy White, Fruitfusion and Freshmint flavours.

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 gum to be used will depend on the smoking habits of the individual. In general, if the patient smokes 20 or less cigarettes a day, the 2mg nicotine gum is indicated. If the patient smokes more than 20 cigarettes a day, the 4mg or 6mg nicotine gum will be needed to meet the withdrawal of the high serum nicotine levels from heavy smoking. The 6mg gum can be recommended particularly to those requiring enhanced craving relief compared to 4mg gum. Nicorette gum 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 gum and as soon as they are able, reduce the number of gums used until they have stopped completely. Smokers aiming to reduce cigarettes should use Nicorette Gum, 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 daily dose: 15 pieces per day. 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 Nicorette Gum are recommended to contact their pharmacist or doctor for advice. For those using the 4 mg gum, switching to the 2 mg gum may be helpful when stopping treatment or reducing the number of gums used each day. The chewing gums should be used whenever there is an urge to smoke according to the "chew and rest" technique described on the pack. After about 30 minutes of such use, the gum will be exhausted.

Contraindications:

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

Precautions:

Underlying cardiovascular disease, diabetes mellitus, G.I disease, hepatic or renal impairment, uncontrolled hyperthyroidism, phaeochromocytoma, keep out of reach and sight of children. Smokers who wear dentures may experience difficulty in chewing. The gum may stick to, and may in rare cases damage dentures. 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 adenosine. See SPCs for further details.

Fertility, Pregnancy and Lactation:

Smoking cessation should be achieved without NRT, however if the mother is unable to quit without pharmacological support, NRT may be used. See SPC for further information.

Side effects:

Very common: headache, cough, sore mouth or throat, throat irritation, nausea, hiccups. Common: hypersensitivity, burning sensation, dizziness, dysgeusia, paraesthesia, abdominal pain, diarrhoea, dry mouth, flatulence, salivary hypersecretion, stomatitis, vomiting, dyspepsia, 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, urticaria, hyperhidrosis, pruritus, rash, pain in jaw, asthenia, chest discomfort and pain, malaise. Rare: dysphagia, hypoaesthesia oral, retching, allergic reactions including angioedema. Very rare: reversible atrial fibrillation. Not known: anaphylactic reaction, blurred vision, lacrimation increased, dry throat, gastrointestinal discomfort, lip pain, erythema, muscle tightness.

RRP NHS Cost: Original 2mg gum (105) £10.27, (210) £16.42, 4mg gum (105) £12.56, (210) £20.28; Icy White 2mg gum (25) £3.52, (105) £10.26, 4mg gum (105) £12.55; Fruitfusion 2mg gum, (105) £10.27; 4mg gum, (105) £12.57; 6mg gum £12.97 (105) £20.81 (210) Freshmint 2mg gum (25) £3.52, (105) £10.27, (210) £16.42; 4mg gum (25) £3.53, (105) £12.56, (210) £20.28.

Legal category: GSL.

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

PL Number(s): Original 2mg 15513/0169, 4mg 15513/0170; Icy White 2mg 15513/0152, 4mg 15513/0153; Fruitfusion 2mg 15513/0136, 4mg 15513/0137, 6mg 15513/0381; Freshmint 2mg 15513/0173, 4mg 15513/0174.

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