

PRODUCT INFORMATION

NICORETTE® CHEWING GUM 2 mg & 4 mg

NAME OF THE DRUG

Nicotine

DESCRIPTION

Nicorette Chewing Gum contains nicotine, added as nicotine polacrilex 20% and is available in two flavours; classic and mint

The chemical name for nicotine is (S)-3-(1-methyl-2-pyrrolidinyl)pyridine. The chemical structure is;

Cas 54-11-5

Nicorette Classic in addition to the active contains:

Sodium carbonate anhydrous

Chewing gum base

Sorbitol powder

Sorbitol solution (70 per cent)

Haverstroo flavour ZD49284

Flavour for Smoker 846422

Glycerol

Talc

The 2 mg classic Chewing Gum also contains sodium bicarbonate. The 4 mg Classic Chewing Gum also contains quinoline yellow CI47005

Nicorette Mint in addition to the active contains:

Sodium carbonate anhydrous

Chewing gum base

Xylitol

Peppermint oil

Menthol

Magnesium oxide light

Talc

The 2 mg mint Chewing Gum also contains sodium bicarbonate. The 4 mg Mint Chewing Gum also contains quinoline yellow CI47005.

PHARMACOLOGY

Nicotine is a natural alkaloid which occurs in the leaves of the tobacco plant. Nicotine has ganglion stimulating properties and therefore produces a wide range of pharmacological actions in the body.

The use of nicotine is widespread in the form of tobacco products, chronic use of which is causally linked to a variety of serious diseases. Many smokers develop a dependence due to an interaction of pharmacological, social and psychological factors.

Nicorette Chewing Gum is a therapeutic agent intended to help smokers break the psychological habit of smoking by reducing the nicotine withdrawal symptoms normally experienced when stopping smoking. As the absorption of nicotine from Nicorette Nicotine Chewing Gum differs from that of a cigarette, the same satisfaction as that obtained from a cigarette will not be achieved. Therefore, once the psychological part of the smoking dependence has been overcome, Nicorette Chewing Gum is usually not difficult to give up.

Pharmacokinetics

When Nicorette Chewing Gum is chewed, nicotine is slowly released into the mouth and is absorbed through the buccal mucosa. A proportion, by the swallowing of nicotine containing saliva, reaches the stomach and intestine and any nicotine absorbed by this route is inactivated. All available nicotine is released from Nicorette Chewing Gum after about 30 minutes of chewing.

INDICATIONS

Smokers who want to give up smoking but who experience difficulty in doing so because of their nicotine dependence.

Note: Motivated patients and medical/professional support will be essential to achieve satisfactory results with Nicorette Chewing Gum.

CONTRAINDICATIONS

Nicorette Chewing Gum should not be administered to non-tobacco users or patients with known hypersensitivity to nicotine or any component of the chewing gum.

Use in pregnancy and lactation

All forms of nicotine should be avoided in pregnancy and by nursing mothers.

Use in children

Nicorette Chewing Gum should not be administered to children

PRECAUTIONS

Dental

Nicorette Chewing Gum has been specially formulated to give it minimum stickiness. However, the degree to which Nicorette Chewing Gum may stick to dentures, dental caps or

partial bridges may depend on the material from which they are made and other factors such as the amount of saliva produced, possible interactions with denture adhesives, denture cleaning compounds, dryness of mouth, salivary constituents and the cleanliness of dentures. Should an excessive degree of stickiness to dental work occur, there is the possibility that, as with other gums, Nicorette Chewing Gum may damage dental work.

Oral

Nicorette Chewing Gum should be avoided if oral or pharyngeal inflammation is present.

Renal impairment

Only severe renal impairment would be expected to affect the clearance of nicotine or its metabolites from the circulation. In patients smoking and undergoing haemodialysis elevated nicotine levels have been seen.

Gastritis or peptic ulcer

Swallowed nicotine may exacerbate symptoms in patients with these conditions.

Cardiovascular disease

The cardiovascular effects of nicotine may be deleterious to patients with angina and coronary heart disease. Nicorette Chewing Gum presents a lesser hazard, however, than smoking, which introduces carbon monoxide as an additional toxic factor.

Dependence

Dependence is a rare side effects and is both less harmful and easier to break than smoking.

Other

Nicorette Nicotine Chewing Gum should be used with caution by patients with:

- * serious cardiac arrhythmia's
- * systemic hypertension
- * peripheral vascular disease
- * hyperthyroidism
- * insulin dependent diabetes
- * phaeochromocytoma
- * recent myocardial infarction

Interactions with other medications and other forms of interaction

Smoking cessation, with or without nicotine substitutes, may alter response to concomitant medication in ex-smokers. Smoking is considered to increase metabolism and thus lower blood levels of drugs such as phenacetin, caffeine, theophylline, imipramine, oxazepam, paracetamol, propranolol and pentazocine, through enzyme induction. Cessation of smoking may result in increased levels of these drugs. Absorption of glutethimide may be decreased and the first pass metabolism of propoxyphene may be decreased by smoking cessation. Other reported effects of smoking, which do not involve enzyme induction, include reduced diuretic effects of frusemide and decreased cardiac output, which may also relate to the hormonal effects of nicotine. The dose of subcutaneous insulin may be required to be decreased at the cessation of smoking, due to an increase in absorption of subcutaneous insulin.

Both smoking and nicotine can increase circulating cortisol and catecholamines. Therapy with adrenergic agonists or with adrenergic blockers may need to be adjusted according to changes in nicotine therapy or smoking status.

ADVERSE REACTIONS

Most of the adverse events reported by users occur during the first weeks after beginning treatment. The adverse events are most likely due to incorrect chewing technique or to the local or systemic pharmacological effects of nicotine, which are dose-dependent.

Note: Some symptoms - such as irritability, sleep disturbances and lightheadedness - reported in connection with the use of Nicorette Chewing Gum may be withdrawal symptoms due to low nicotine levels. Aphthous ulcers may occur in connection with smoking cessation but the relation to nicotine replacement therapy is unclear.

Patients who continue smoking when using the Nicorette Chewing Gum may experience adverse effects due to peak nicotine levels higher than those experienced from smoking alone.

Incidence, more frequent (> 1/100)

CNS: Dizziness, headache

GI: Nausea, gastrointestinal discomfort, hiccups, jaw-muscle ache, sore mouth or throat

Other: Maintained nicotine dependence after smoking cessation.

Incidence, less frequent (1/100-1/1000)

Cardiovascular: Rapid or irregular heart beat, paraesthesia, palpitations

Dermatological: Erythema, urticaria

Incidence, rare (<1/1000)

Cardiovascular: Reversible atrial fibrillation

DOSAGE AND ADMINISTRATION

The strength of Nicorette Nicotine Chewing Gum should be chosen according to the smoker's tobacco dependence. Highly dependent smokers, and smokers who have failed to quit when using 2 mg, should use the 4 mg strength. Otherwise, the 2 mg strength should be used. Nicorette Chewing Gum should be used when the urge to smoke is felt. Most smokers require about 16-24 mg of nicotine daily (8-12 pieces of the 2 mg gum or 4-6 pieces of the 4 mg gum). Not more than 40 mg (20 pieces of the 2 mg gum or 10 pieces of the 4 mg gum) of nicotine should be chewed in one day. The duration of treatment is individual. Clinical experience has shown that the treatment should last for at least 3 months. The nicotine dose should then be gradually reduced. The treatment should be stopped when the daily

consumption is down to 1-2 pieces of gum. However, it is suggested that smokers carry Nicorette Chewing Gum with them for those rare occasions when there is an urge to smoke.

The use of Nicorette Chewing Gum beyond one year is not recommended.

The following points should be observed:

Due to its nicotine content, Nicorette Chewing Gum has an unusual taste. Nicorette Chewing Gum should be chewed slowly until a strong taste or a slight tingling sensation is felt. When the tingling sensation occurs the smoker should stop chewing and the gum should be placed under the tongue or between the cheek and gums until the taste or tingling sensation has disappeared. Chewing should then be resumed slowly and the procedure repeated. Nicorette Chewing Gum should be chewed in this manner until the nicotine effect is no longer experienced (about 30 minutes). The nicotine effects are not experienced until after a few minutes of chewing, the rapid satisfaction supplied by smoking is hence not to be expected. Rapid chewing may initially irritate the throat or cause hiccups or nausea. Adapting to the proper chewing technique takes a few days. Acidic beverages, e.g. coffee or soft drinks interfere with the buccal absorption of nicotine. Use of such beverages should therefore be avoided for 15 minutes before and during chewing.

OVERDOSAGE

Overdosage could occur if many pieces are chewed simultaneously or in rapid succession. The risk of poisoning as a result of swallowing the chewing gum is very small as absorption in the absence of chewing is slow and incomplete. Moreover, any nicotine that is absorbed will be inactivated in the liver. The consequences of an overdose especially from chewing are most likely to be minimised by the early nausea and vomiting known to occur with excessive nicotine intake. However, toxic systemic effects may develop. The fatal acute dose of nicotine in man is from 40 to 60 mg.

Should an overdose occur, the symptoms would be those of acute nicotine poisoning. Symptoms and signs include nausea, salivation, abdominal pain, vomiting, diarrhoea, cold sweat, headache, dizziness, disturbed hearing and vision, mental confusion and marked weakness.

Faintness and prostration will likely ensue and hypotension may occur; breathing is difficult; the pulse may be rapid, weak and irregular; circulatory collapse may be followed by terminal convulsions. Death may result within a few minutes from respiratory failure caused by paralysis of the muscles of respiration.

Management of overdose

In the event of swallowing large quantities of Nicorette Nicotine Chewing Gum, vomiting should be induced with syrup of ipecacuanha and/or gastric lavage carried out (wide bore tube). A suspension of activated charcoal should then be passed through the tube and left in the stomach. Artificial respiration with oxygen should be instituted if needed and continued for as long as is necessary. Other therapy, including treatment of shock, is purely symptomatic.

PRESENTATION

Chewing Gum, classic and mint, 2 mg (beige): blister packs of 30's, 105's

Chewing Gum, classic and mint, 4 mg (yellow): blister packs of 30's , 105's

NAME AND ADDRESS OF THE SPONSOR

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