Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

NCH Mint G 2 mg, uncoated medicated chewing-gum.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

One piece of medicated chewing-gum contains 2 mg nicotine (as 10 mg nicotine-polacrilin (1:4)).

For excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Medicated Chewing-gum.

Each piece of uncoated chewing-gum is off-white in colour and rectangular in shape.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

NCH treatment is indicated for the relief of nicotine withdrawal symptoms, in nicotine dependency as an aid to smoking cessation.

4.2 Posology and method of administration

Adults and elderly

Users should stop smoking completely during treatment with NCH gum. One piece of NCH gum to be chewed when users feel the urge to smoke.

Normally, 8-12 pieces per day, up to a maximum of 25 pieces per day.

The 2 mg chewing-gum may not be well suited to smokers with a strong or very strong nicotine dependency.

The characteristics of chewing-gum as a pharmaceutical form are such that individually different nicotine levels can result in the blood. Therefore, dosage frequency should be adjusted according to individual requirements within the stated maximum limit.

Directions for use

1. One piece of gum should be chewed until the taste becomes strong.
2. The chewing-gum should be rested between the gum and cheek.
3. When the taste fades, chewing should commence again.
4. The chewing routine should be repeated for 30 minutes.

The treatment time is individual. Normally, treatment should continue for at least 3 months. After three months, the user should gradually cut down the number of pieces chewed each day until they have stopped using the product.

Treatment should be discontinued when the dose has been reduced to 1-2 pieces of gum per day. Use of nicotine products like NCH gum beyond 6 months is generally not recommended.

Some ex-smokers may need treatment with the gum for longer to avoid returning to smoking.

Patients who have been using oral nicotine replacement therapy beyond 9 months are advised to seek additional help and information from health care professionals.

Counselling may help smokers to quit.

NCH gum is sugar free.

Children

Not to be used by children.

Concomitant use of acidic beverages such as coffee or soda may interfere with the buccal absorption of nicotine. Acidic beverages should be avoided for 15 minutes prior to chewing the gum.

4.3 Contraindications

Hypersensitivity to any excipients of the gum.

NCH gum should not be used by non-smokers or people under 18 years of age.

Use is contra-indicated, in patients during the immediate post-infarction period, unstable or worsening angina pectoris (including Prinzmetal's angina), severe cardiac arrhythmias and recent cerebrovascular accident.

4.4 Special warnings and precautions for use

Swallowed nicotine may exacerbate symptoms in subjects suffering from active oesophagitis, oral or pharyngeal inflammation, gastritis or peptic ulcer.

Use with caution in patients with hypertension, stable angina pectoris, cerebrovascular disease, occlusive peripheral arterial disease, heart failure, hyperthyroidism, diabetes mellitus, fructose intolerance, pheochromocytoma and renal or hepatic impairment.

To improve the chance of successfully quitting smoking, the use of the medicated gum should be accompanied by cessation of smoking. Counselling may help smokers to quit.

Doses of nicotine that are tolerated by adult smokers during treatment may produce severe symptoms of poisoning in small children and may prove fatal (please see section 4.9).

If denture wearers experience difficulty in chewing the gum it is recommended that they use a different pharmaceutical form of nicotine replacement therapy.

Patients with rare hereditary problems of fructose intolerance should not take this medicine.

NCH Mint 2 mg uncoated chewing-gum contains sorbitol (E420) 0.2 g per chewing-gum, a source of 0.04 g fructose. Calorific value 0.5 kcal/piece of chewing-gum.

NCH Mint 2 mg uncoated chewing-gum contains sodium 11.54 mg per piece.

4.5 Interaction with other medicinal products and other forms of interaction

Drug Interactions

No information is available on interactions between NCH gum and other drugs.

Smoking Cessation

This is different in the case of smoking where interactions with other medications may occur due to a multitude of other substances contained in the smoke. Presumably due to the polycyclic aromatic hydrocarbons contained in the smoke, the metabolism of different medicinal products may be speeded up by enzyme induction: e.g. caffeine, theophylline, paracetamol, phenazone, phenylbutazone, pentazocine, lidocaine, benzodiazepines, imipramine, warfarin, oestrogen and vitamin B12.

Upon smoking cessation it may be expected that the hitherto increased metabolism of these medicinal products is slowed down or normalised. Unaltered dosage of the products may result in an increase in their blood concentration. Therefore when using NCH gum a possible dose reduction should be considered in patients treated with the above mentioned medicinal products.

Other reported effects of smoking include a reduction of the analgesic effects of propoxyphene, reduced diuretic response to furosemide, change in the pharmacological effect of propanolol and altered responder rates in ulcer healing with H_2-antagonists.

Smoking and nicotine may raise the blood levels of cortisol and catecholamines. Dose adjustment of nifedipine, adrenergic agonists or adrenergic antagonists may be necessary.

Increased subcutaneous absorption of insulin which occurs under smoking cessation may necessitate a reduction in insulin dose.

4.6 Pregnancy and lactation

Pregnancy

In the pregnant smoker the aim should be to achieve complete cessation of smoking before the third trimester of pregnancy due to the perinatal risk. Smoking continued during the third trimester may lead to intra-uterine growth retardation or even premature birth or stillbirth, depending on the daily amount of tobacco.

Consequently,

- In pregnant women complete cessation of tobacco smoking should always be recommended without nicotine replacement therapy;
- Nevertheless, in the case of failure in highly dependent pregnant smokers, tobacco withdrawal via nicotine replacement therapy may be recommended. Indeed, fetal risk is probably lower than that expected with tobacco smoking, due to:
- Lower maximal plasma nicotine concentration than with inhaled nicotine
- No additional exposure to polycyclic hydrocarbons and carbon monoxide
- Improved chances of quitting smoking by the third trimester

Tobacco withdrawal with or without nicotine replacement therapy should not be undertaken alone but as part of a medically supervised smoking cessation program.

In the third trimester nicotine has haemodynamic effects (e.g. changes in fetal heart rate) which could affect the fetus close to delivery. In view of this, the gum should only be used after the sixth month of pregnancy under medical supervision in pregnant smokers who have failed to stop smoking by the third trimester.

Lactation

Nicotine is excreted in breast milk in quantities that may affect the child even in therapeutic doses. The gum, like smoking itself, should therefore be avoided during breast feeding. Should smoking withdrawal not be achieved, use of the gum by breast feeding smokers should only be initiated after advice from a physician. Where nicotine replacement therapy is used whilst breast-feeding, the gum should be taken just after breast feeding and not during the two hours before breast feeding.

4.7 Effects on ability to drive and use machines

Smoking cessation can cause behavioural changes. There is no evidence of any risks associated with driving or operating machinery when the gum is used following the recommended dose.

4.8 Undesirable effects

In principle, NCH gum can cause adverse reactions similar to those associated with nicotine administered by smoking.

Common
CNS: headache, dizziness.
GI: hiccups, gastric symptoms e.g. nausea, vomiting, indigestion, heartburn.
Local: increased salivation, irritation or sore mouth or throat, jaw muscle ache, the gum may stick to and in rare cases damage dentures and dental appliances.

Less Common
Cardiovascular: palpitations.
Skin: erythema, urticaria.

Rare
Cardiovascular: cardiac arrhythmias (e.g. atrial fibrillation).
Others: hypersensitivity, angioneurotic oedema and anaphylactic reactions.

4.9 Overdose

In overdose, symptoms corresponding to heavy smoking may be seen.

The acute lethal oral dose of nicotine is about 0.5 - 0.75 mg per kg body weight, corresponding in an adult to 40 - 60 mg.

Even small quantities of nicotine are dangerous in children, and may result in severe symptoms of poisoning which may prove fatal. If poisoning is suspected in a child, a doctor must be consulted immediately.

Overdose with NCH gum may only occur if many pieces are chewed simultaneously. Risk of overdose is small as nausea or vomiting usually occurs at an early stage. Risk of poisoning by swallowing the gum is small. Since the release of nicotine from the gum is slow, very little nicotine is absorbed from the stomach and intestine, and if any is, it will be inactivated in the liver.

General symptoms of nicotine poisoning include: weakness, perspiration, salivation, throat burn, nausea, vomiting, diarrhoea, abdominal pain, hearing and visual disturbances, headache, tachycardia and cardiac arrhythmia, dyspnoea, prostration, circulatory collapse, coma and terminal convulsions.

Treatment of overdose

Following overdose, symptoms may be rapid particularly in children. Emesis is usually spontaneous. Administration of oral activated charcoal and gastric lavage should be considered as soon as possible and within 1 hour of ingestion. Monitor vital signs and treat symptomatically.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

ATC Code*:* N07B A01

Pharmacotherapeutic group: Drugs used in nicotine dependence.

Nicotine gum mimics the pharmacological effects of nicotine from smoking and may therefore be used to help provide relief from nicotine withdrawal symptoms.

In addition to effects on the central nervous system, nicotine produces haemodynamic effects such as increased heart rate and systolic blood pressure.

5.2 Pharmacokinetic properties

When the gum is chewed, nicotine is steadily released into the mouth and is rapidly absorbed through the buccal mucosa. A proportion, by the swallowing of nicotine containing saliva, reaches the stomach and intestine where it is inactivated.

The peak plasma concentration of the 2 mg gum after a single dose is approximately 4.8 nanograms per ml and following steady state administration is approximately 14 nanograms per ml (average plasma concentration of nicotine when smoking a cigarette is 15-30 nanograms per ml). For a Chewing-gum of 4 mg it has been calculated that a maximum plasma concentration of approximately 10 ng/ml is reached after approximately 30 minutes.

Nicotine is eliminated mainly via hepatic metabolism; small amounts of nicotine are eliminated in unchanged form via the kidneys. The plasma half-life is approximately three hours. Nicotine crosses the blood-brain barrier, the placenta, and is detectable in breast milk.

5.3 Preclinical safety data

No animal studies have been undertaken on NCH Chewing-gum.

The toxicity of nicotine as a constituent of tobacco has been well documented. Acute toxic effects include convulsions, cardiac insufficiency, and paralysis of the respiratory system.

At high doses in cats and dogs, nicotine has been shown to potentiate histamine-induced peptic ulcer.

Nicotine has no genotoxic activity in most of the mutagenicity test systems. The well-known carcinogenicity of tobacco smoking is mainly caused by pyrolysis products. Application of nicotine chewing-gum, however, avoids the high temperature required for the formation of these carcinogenic products.

All excipients used in NCH Chewing-gum are of food or pharmaceutical grade.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Gum base
Calcium carbonate
Sorbitol (E420)
Purified water
Glycerol
Sodium carbonate anhydrous
Sodium hydrogen carbonate
Polacrilin
Levomenthol
Peppermint Oil
Eucalyptus Oil
Butylhydroxytoluene (E321)
Acesulfame potassium
Saccharine
Sodium saccharine
Talcum powder
Carnauba wax.

6.2 Incompatibilities

Not applicable.

6.3 Shelf Life

2 years.

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container

The chewing-gum is packed in PVC/aluminium blister packs each containing 12 pieces of gum. The blisters are packed in boxes containing 12, 24, 36, 48, 60, 72, and 96 pieces of gum.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

No special requirements.

7 MARKETING AUTHORISATION HOLDER

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