New Zealand Data Sheet

1 HABITROL 1 mg, 2 mg lozenge

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Habitrol Lozenge contains 1 mg or 2 mg of nicotine in a lozenge formulation.

Each 1 mg lozenge contains 3.072 mg nicotine bitartrate dihydrate (equivalent to 1 mg nicotine).
Each 2 mg lozenge contains 6.144 mg nicotine bitartrate dihydrate (equivalent to 2 mg nicotine).

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Lozenges are white and round in shape and available in mint flavour.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Habitrol Lozenge is indicated for the relief of nicotine withdrawal symptoms in nicotine dependency, as an aid to smoking cessation. Habitrol Lozenge may be used as part of a smoking reduction strategy by smokers who are unable or not ready to stop smoking abruptly, as a step towards stopping completely. Habitrol Lozenge may be used by smokers who are unable or not ready to quit on occasions when temporary abstinence from smoking is desired.

4.2 Dose and method of administration

Dose

Quit Now Program

The patient should be advised to stop smoking completely when starting the Habitrol Quit Now Program.

The strength of Habitrol Lozenge should be chosen according to the smoker's tobacco dependence. Highly dependent smokers (those smoking 20 or more cigarettes per day), as well as smokers who have failed to quit when using the 1 mg lozenge, should use the 2 mg lozenge. Otherwise, the 1 mg strength should be used.

One lozenge should be sucked slowly when the user feels the urge to smoke. Patients should not use more than 1 lozenge at a time. The number used should typically be 8-12 lozenges per day, up to a maximum of 24 of the 1 mg lozenge or 15 of the 2 mg lozenge per day.

Patients should not use more than 1 lozenge per hour.

Use in children under 18 years

The use of NRT in adolescents should only be used when the benefits of abstinence outweigh the risks of continued smoking.

Adolescents aged 12 to 17 years should only use Habitrol Lozenge with the advice of a healthcare professional. Adolescents should follow the schedule of treatment for 'Quit Now Program' as given above. After about 8 weeks, gradually reduce to 1 to 2 lozenges a day and then stop completely.Treatment should not exceed 12 weeks without consultation with a healthcare professional. Before recommending use of NRT beyond 12 weeks in this age group, the healthcare professional should reassess the user's commitment to smoking cessation and the likely benefit of continued treatment; treatment should not be extended by more than a further 4 weeks.

Do not use in children under 12 years.

Instructions for use

Concomitant use of acidic beverages, such as coffee or soft drinks, may interfere with the buccal absorption of nicotine. Acidic beverages should be avoided for 15 minutes prior to using the lozenge and users should not eat or drink while a lozenge is in the mouth

1. Suck one lozenge slowly until the taste becomes strong
2. Rest the lozenge between the gum and cheek
3. When the taste fades, recommence sucking
4. This routine should be repeated for 30 minutes.

After 3 months, users should gradually cut down the number of lozenges used each day until only 1-2 lozenges per day are required, at which time they should stop using the product. This process may take 6 months from the start of treatment. Counselling may help smokers to quit. Those using NRT for more than 9 months should seek advice from a healthcare professional. Use of the product beyond 9 months is only if the potential benefit outweighs the potential risk to the smoker.

Reduce to Quit Program (gradual cessation of smoking)

For smokers who are unwilling or unable to suddenly quit smoking, Habitrol Lozenge may be used whenever there is an intense desire to smoke, to help reduce the number of cigarettes smoked before stopping smoking completely. The smoker should attempt a reduction in cigarette consumption as soon as possible. Consult a healthcare professional if the number of cigarettes smoked has not been reduced in 6 weeks. Once the number of cigarettes has been reduced to a point where the smoker can quit completely, then the Habitrol Lozenge Quit Now Program should be followed. Consult a healthcare professional if an attempt to stop smoking completely has not commenced within 6-9 months of beginning treatment. Use of the product beyond 9 months is only if the potential benefit outweighs the potential risk to the smoker.

Combination therapy

If a smoker has previously relapsed with use of a single form of nicotine replacement therapy (NRT), combination therapy could be beneficial. Smokers who experience breakthrough cravings or have difficulty controlling cravings using one form of NRT alone may combine the use of Habitrol Patches Step 1 with Habitrol Lozenge 1 mg. Habitrol Lozenge 2 mg should not be used with Habitrol Patches.

When using Habitrol Patches Step 1 in addition to Habitrol Lozenge 1 mg, it is recommended that 4-12 lozenges are used each day. Most people will use 5-6 lozenges. Do not exceed 12 lozenges a day.

Combination Therapy should be used for 12 weeks, after which one of the two following programs should be followed:

1. Stop use of Habitrol Patches and gradually reduce the number of Habitrol Lozenge used until no longer needed.
2. Continue with Habitrol Patches Step 2 for 3-4 weeks, then Habitrol Patch Step 3 for a further 3-4 weeks while maintaining the number of Habitrol Lozenge 1 mg used each day. After use of patches is ceased, gradually reduce the number of lozenges used until no longer needed.

Users should stop smoking completely during treatment with Habitrol Lozenge 1 mg in combination with Habitrol patches.

Adolescents aged 12 to 17 years should not quit using combination therapy.

Temporary abstinence

Smokers who are unable or not ready to quit may use Habitrol Lozenge on occasions when temporary abstinence from smoking is required (for example, in smoke-free areas, at their place of work, on a plane or in other situations where they cannot or choose not to smoke, and there is an urge to smoke).

Refer to “Dose” to select the most appropriate Habitrol Lozenge strength based on daily cigarette usage. After 6 weeks, if you have not cut down the number of cigarettes you smoke each day, see your doctor or pharmacist. Use of the product beyond 9 months is only if the potential benefit outweighs the potential risk to the smoker.

4.3 Contraindications

Habitrol Lozenge should not be used by non-smokers, children under 12 years or those with known hypersensitivity to nicotine or any of the excipients in the lozenge.

4.4 Special warnings and precautions for use

Nicotine is a toxic and addictive drug and doses of only milligrams are potentially fatal if rapidly absorbed. For any smoker, with or without concomitant disease or pregnancy, the risk of NRT

use in a smoking cessation program should be weighed against the hazard of continued smoking and the likelihood of achieving cessation of smoking without NRT.

Treatment with Habitrol Lozenge should be discontinued if symptoms of nicotine overdose appear. Mild intoxication produces nausea, vomiting, abdominal pain, diarrhoea, headache, sweating, and weakness (see Overdosage).

Therapeutic doses of nicotine that are tolerated by adult smokers can produce severe symptoms of poisoning in small children and may prove fatal (see Overdosage). Habitrol Lozenge must be kept out of sight and reach of children at all times.

Nicotine-dependent smokers with a recent myocardial infarction, severe cardiac arrhythmias, or recent cerebrovascular accident who are considered to be haemodynamically unstable should be encouraged to stop smoking with non-pharmacological interventions (such as counselling). If this fails, Habitrol may be considered, but as data on safety in these patient groups are limited, initiation should only be under close medical supervision. If there is a clinically significant increase in cardiovascular or other effects attributable to nicotine, lozenge use should be reduced or discontinued.

Combination therapy should not be used in people with known cardiovascular disease without evaluation of the risk/benefit by a healthcare professional.

Habitrol should be used with caution in patients with:

- severe hypertension, stable angina pectoris, cerebrovascular disease, occlusive peripheral arterial disease, heart failure
- hyperthyroidism or phaeochromocytoma,
- moderate to severe hepatic impairment and/or moderate to severe renal impairment; active peptic ulcer.

Smokers with diabetes mellitus should be advised to monitor their blood sugar levels more closely than usual when NRT is initiated because catecholamine release can affect carbohydrate metabolism and vasoconstriction may delay or reduce insulin absorption. Blood sugar levels may be more variable during smoking cessation, with or without NRT.

Seizures: potential risk and benefits of nicotine should be carefully evaluated before use in patients taking anti-convulsant therapy or with a history of epilepsy as cases of convulsions have been reported in association with nicotine.

Swallowed nicotine may exacerbate symptoms in patients with active oesophagitis, gastritis, gastric ulcer or peptic ulcer. Avoid use of Habitrol Lozenge if oral or pharyngeal inflammation is present.

Special warnings about excipients

Habitrol Lozenge contains galactose and sulfites.

Because Habitrol Lozenge contains maltitol, patients with rare hereditary conditions of fructose intolerance should not take this medicine.

Each lozenge contains 11.5 mg sodium per lozenge (equivalent to 276.2 mg per maximum dose of 24 Habitrol Lozenge 1 mg or equivalent to 172.6 mg per maximum dose of 15 Habitrol Lozenge 2 mg), which should be taken into account by those on a low-sodium diet.

Each lozenge contains 0.88 g maltitol per lozenge (equivalent to 21.1 g per maximum dose of 24 Habitrol Lozenge 1 mg or equivalent to 13.2 g per maximum dose of 15 Habitrol Lozenge 2 mg). Products containing maltitol may have a laxative effect or cause diarrhoea.

Each 1 mg and 2 mg lozenge contains 0.01 g aspartame, a source of phenylalanine, which may be harmful for people with phenylketonuria.

Paediatric population

Data on the use of NRT in treating adolescents under the age of 18 years are limited.

NRT should be used in adolescents 12 to 17 years only after consultation with a healthcare professional and use should be restricted to 12 weeks. If treatment is required for longer than 12 weeks, this should be discussed with a healthcare professional.

Do not use in children under 12 years.

4.5 Interaction with other medicines and other forms of interaction

No information is available on interactions between Habitrol Lozenge and other medicines. Smoking cessation itself may require adjustment of some drug therapy.

Smoking is associated with increase in CYP1A2 activity. After cessation of smoking, reduced clearance of substrates for this enzyme may occur. This may lead to an increase in plasma levels for some medicinal products that may be of potential clinical importance for products with a narrow therapeutic window, e.g. theophylline, tacrine, clozapine and olanzapine.

The plasma concentration of other drugs metabolised in part by CYP1A2, e.g. caffeine, paracetamol, phenazone, phenylbutazone, pentazocine, lidocaine, benzodiazepines, warfarin, oestrogen and vitamin B12, may also increase on cessation of smoking. However, data to support this are lacking and any possible clinical significance of this effect for these drugs is unknown.

Smoking may lead to reduced analgesic effects of propoxyphene, reduced diuretic response to furosemide (frusemide), reduced effect of propranolol on blood pressure and heart rate and reduced responder rates in ulcer healing with H_2 antagonists.

Smoking or other nicotine administration may raise the blood levels of cortisol and catecholamines, i.e. may lead to a reduced effect of nifedipine or adrenergic antagonists, and to an increased effect of adrenergic agonists.

Increased subcutaneous absorption of insulin occurs upon smoking cessation and may necessitate a reduction in insulin dose.

4.6 Pregnancy and lactation

Pregnancy (Category D)

Adverse reproductive and developmental effects have been reported following exposure to tobacco and nicotine during pregnancy. In pregnant women, complete cessation of tobacco consumption should always be recommended, without NRT use. However, for women unable to quit on their own, NRT may be recommended to assist a quit attempt, if the expected benefits to the mother outweigh the potential risks to the foetus. Nicotine is harmful to the foetus. However, the foetal risk is expected to be less than that of continued smoking due to:

- Lower maximal plasma concentrations with NRT compared with inhaled nicotine, resulting in nicotine exposure lower or no more than that associated with smoking.
- No exposure to cigarette polycyclic hydrocarbons and carbon monoxide with NRT.

As nicotine does pass to the foetus, the decision to use NRT should be made as early on in pregnancy as possible with the aim of discontinuing after use for 2-3 months.

If NRT is used during pregnancy, HABITROL Lozenge or Chewing Gum should preferentially be used as intermittent products usually provide a lower daily dose of nicotine than patches. However, if the woman suffers from nausea and/or vomiting, the patch may be recommended but should be removed before going to bed.

Breast-feeding

Even in therapeutic doses, nicotine is excreted in breast milk in quantities that may affect the child. Like smoking, NRT should be avoided during breast-feeding. However should smoking withdrawal not be achieved, Habitrol Lozenge or Gum may be used if necessary. However, oral forms of NRT should only be used if the expected benefits to the nursing mother outweigh the potential risks to the infant. Women should breastfeed just before they use the product to allow the time between NRT use and breastfeeding to be as long as possible.

4.7 Effects on ability to drive and use machines

Smoking cessation can cause behavioural changes. Any risks associated with driving vehicles or operating machinery are considered minimal when the lozenges are used according to the recommended dose.

4.8 Undesirable effects

Habitrol Lozenge can cause adverse reactions similar to those associated with nicotine administered in other ways. These can be attributed to the pharmacological effects of nicotine, which are dose-dependent.

Most of the side effects that are reported by patients occur generally during the first 3-4 weeks after initiation of therapy.

Nicotine from lozenges may sometimes cause a slight irritation of the throat and increase in salivation at the start of treatment. Excessive swallowing of released nicotine in the saliva may, at first, cause hiccups. Those with a tendency to indigestion may suffer initially from slight dyspepsia or heartburn. Slower sucking will usually overcome this problem.

Excessive consumption of lozenges by non-smokers, may lead to nausea, faintness and headache.

Increased frequency of aphthous ulcer may occur after abstinence from smoking.

Adverse reactions are listed below, by system organ class and frequency. Frequencies are defined as: very common (≥1/10), common (≥1/100 to <1/10), uncommon (≥1/1,000 to <1/100), rare (≥1/10,000 to <1/1,000) or very rare (<1/10,000).

Nervous system disorders:	Common: headache*, dizziness* Rare: Tremor
Gastrointestinal disorders:	Very common: nausea Common: flatulence, hiccups, gastritis, dryness of the mouth, irritation/discomfort of the oral cavity and oesaphagus, vomiting, dyspepsia, upper abdominal pain, diarrhoea, constipation, stomatitis, salivary hypersecretion. Rare: dysphagia, eructation
Cardiac disorders:	Uncommon: palpitations, tachycardia, arrhythmias Rare: atrial arrhythmia
Immune system disorders:	Uncommon: urticaria Rare: hypersensitivity, angioneurotic oedema and anaphylactic reactions, ulcerative stomatitis
Psychiatric disorders	Common: insomnia*
Respiratory, Thoracic and Mediastinal Disorders	Common: Pharyngitis, cough*, pharyngolaryngeal pain Rare: Dyspnoea

General disorders and Administration site conditions.	Rare: Asthenia*, fatigue*, malaise*, influenza type illness*

*These events may also be due to withdrawal symptoms following smoking cessation.

Certain symptoms such as dizziness, headache and insomnia may be ascribed to withdrawal symptoms from smoking cessation and may be due to insufficient administration of NRT.

Cold sores may develop in association with smoking cessation, but any relationship with NRT is unclear.
The patient may continue to experience nicotine dependence after smoking cessation.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare professionals are asked to report any suspected adverse reactions https://pophealth.my.site.com/carmreportnz/s/

4.9 Overdose

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

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

Risk of overdose is small as nausea or vomiting usually occurs at an early stage. Overdose with Habitrol Lozenge is likely only if many lozenges are sucked simultaneously.

Signs and symptoms of an overdose from Habitrol Lozenge would be expected to be the same as those of acute nicotine poisoning, including pallor, salivation, hyperhidrosis, vomiting, abdominal pain, diarrhoea, headache, dizziness, sensory disturbance, tremor, confusional state and asthenia.

Prostration, hypotension, circulatory collapse, respiratory failure and convulsions may ensue with large overdoses.

Treatment of Overdose

Seek immediate medical advice or contact the National Poisons Centre on 0800 POISON (0800 764 766)

In the event of an overdose, medical attention should be sought immediately. All nicotine intake should stop immediately and the patient should be treated symptomatically, and vital

signs monitored. Activated charcoal may reduce absorption of the medicine if given within one or two hours after ingestion. In patients who are not fully conscious or have impaired gag reflex, consideration should be given to administering activated charcoal via a nasogastric tube, once the airway is protected.

Further management should be as clinically indicated or as recommended by the Poisons Information Centre.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: drugs used in nicotine dependence, ATC code: N07BA01

Mechanism of action

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

5.2 Pharmacokinetic properties

The quantity of nicotine absorbed depends on the amount released into the mouth and absorbed across the buccal mucosa.

The majority of nicotine in Habitrol Lozenge is absorbed through the buccal mucosa. A proportion of nicotine reaches the stomach, by the swallowing of nicotine containing saliva, where it is inactivated. Due to the first-pass effect in the liver, the systemic bioavailability of nicotine is low. Consequently, in treatment with Habitrol Lozenge the high and rapid systemic nicotine concentration occurring when smoking is rarely obtained.

Distribution volume after intravenous administration of nicotine is approximately 2-3 L/kg and the half-life is 2 hours. Nicotine is metabolised principally in the liver and the plasma clearance is approximately 1.2 L/min; nicotine is also metabolised in the kidney and lungs. Nicotine crosses the blood-brain barrier.

More than 20 metabolites have been identified, all believed to be less active than nicotine. The main metabolite is cotinine, which has a half-life of 15-20 hours and a plasma concentration approximately 10 times higher than nicotine. Nicotine's plasma protein binding is less than 5%. Changes in nicotine binding with the use of concomitant drugs or altered disease states are not expected to significantly affect nicotine kinetics. The main metabolites in urine are cotinine (15% of the dose) and trans-3-hydroxycotinine (45% of the dose).
About 10% of the nicotine is excreted unchanged. Up to 30% may be excreted in urine with increased diuresis and acidity (under pH 5.0).

The peak plasma nicotine concentration following a single dose of 1 mg lozenge is approximately 4 ng/mL. The maximal concentration at steady state is approximately 10.6

ng/mL. Peak plasma nicotine concentration is reached after about 45 minutes following sucking of a single 1 mg lozenge and after about 30 minutes at steady state.

The peak plasma nicotine concentration following a single dose of 2 mg lozenge is approximately 7 ng/mL. The maximal concentration at steady state is approximately 22.5 ng/mL. Peak plasma nicotine concentration is reached after about 48 minutes following sucking of a single 2 mg lozenge and after about 30 minutes at steady state.

The average plasma nicotine concentration after smoking one cigarette is 15-30 ng/mL.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Each lozenge contains the following excipients:

Maltitol
Sodium carbonate anhydrous
Sodium hydrogen carbonate
Polyacrylate dispersion 30%
Xanthan gum
Menthol
Peppermint oil
Aspartame
Magnesium stearate
Colloidal Silicon Dioxide

6.2 Incompatibilities

Not applicable

6.3 Shelf life

2 years

6.4 Special precautions for storage

Store below 25ºC. Store in the original package.

6.5 Nature and contents of container

Boxes containing 36 or 216 lozenges (12 lozenges per blister pack).
Not all pack sizes may be marketed.

6.6 Special precautions for disposal

No special requirements.

7 MEDICINE SCHEDULE

General Sale Medicine

8 SPONSOR

Haleon New Zealand ULC
Private Bag 106600
Downtown
Auckland 1143
New Zealand
FREECALL NZ: 0800 540 144

9 DATE OF FIRST APPROVAL

24 July 2008

10 DATE OF REVISION OF THE TEXT

28 March 2024

SUMMARY TABLE OF CHANGES

Section changed	Summary of new information
4.2	Updates throughout to dose and instructions for use sections
4.4	Updates throughout to numerous warnings/precautions for use
4.5	Addition of the statement 'Smoking cessation itself may require adjustment of some drug therapy
4.6	Updates throughout 'Pregnancy' and 'Breastfeeding' sections
4.8	Additions and changes to adverse reactions table; change to adverse reactions reporting website
4.9	Updates throughout 'Overdose' and 'Treatment of overdose' sections
6.1	To align with current registered details, addition of 'colloidal silicon dioxide'; change from 'Polyacrylate dispersion 30% (colloidal anhydrous) to 'Polyacrylate dispersion 30%'