AUSTRALIA PRODUCT INFORMATION

NICORETTE® LOZENGE (NICOTINE)
2 mg & 4 mg

1 NAME OF THE MEDICINE

Nicotine

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

NICORETTE® Lozenge contains nicotine, added as nicotine polacrilex and is available as icy mint and fruit flavoured lozenges in 2mg and 4mg strengths.

NICORETTE® Lozenge also contains sucralose and mannitol.

For the full list of excipients, see Section 6.1 List of excipients.

3 PHARMACEUTICAL FORM

NICORETTE® Lozenge is an oval, white to off-white film-coated lozenge with a size of about 14 x 9 x 7 mm, imprinted with "n" on one side and “2” on the other side of the 2mg lozenge, and “4” on the other side of the 4mg lozenge.

4 CLINICAL PARTICULARS

4.1 THERAPEUTIC INDICATIONS

For the treatment of tobacco dependence by relieving nicotine craving and withdrawal symptoms, thereby facilitating smoking cessation in smokers motivated to quit.

In smokers currently unable or not ready to stop smoking abruptly, NICORETTE® Lozenge may also be used as part of a smoking reduction strategy as a step towards stopping completely.

4.2 DOSE AND METHOD OF ADMINISTRATION

Smoking cessation

The initial dosage should be individualised on the basis of the patient’s nicotine dependence. NICORETTE® Lozenge should be used when the urge to smoke is felt.

NICORETTE® Lozenges 2 mg are suitable for smokers with a low nicotine dependency e.g. those smoking their first cigarette of the day more than 30 minutes after waking up, or those who smoke fewer than 20 cigarettes per day.

NICORETTE® Lozenges 4 mg are suitable for smokers with a high nicotine dependency e.g. those smoking their first cigarette of the day within 30 minutes after waking up, or those who smoke more than 20 cigarettes per day.

One lozenge should be placed in the mouth and allowed to dissolve. Periodically the lozenge should be moved from one side of the mouth to the other, and repeated, until the lozenge is completely dissolved (approximately 16-19 minutes). The lozenge should not be chewed or swallowed.

Users should not eat or drink while a lozenge is in the mouth. Liquids which lower pH in the mouth such as coffee, juice and soft drinks, can decrease the absorption of nicotine in the mouth. To obtain maximum absorption of nicotine these liquids should be avoided for up to 15 minutes before the lozenge is used.

Children

NICORETTE® Lozenge should not be administered to children under 12 years of age.

Adults and elderly

The initial dosage should be individualised on the basis of the patient's nicotine dependence. Most smokers require 8 to 12 lozenges per day. Not more than 15 lozenges should be used in one day. The duration of treatment is individual, but up to three months treatment is recommended to break the habit of smoking. The nicotine dose should then be gradually reduced, by decreasing the total numbers of lozenges per day. The treatment should be stopped when the dose is reduced to 1 to 2 lozenges per day. Any spare lozenges should be retained as craving may suddenly occur.

Regular use of the lozenge beyond 9 months is generally not recommended. Smokers who use NICORETTE® Lozenges beyond 9 months are recommended to seek additional help and advice from a healthcare professional.

Adolescents (12 to 18 years)

When deciding whether to recommend NRT an assessment should be made on the individual's nicotine dependence, motivation to quit and willingness to accept counselling. Counselling is considered to be vitally important in the effective treatment of tobacco dependence in this age group.

Use for up to 8 weeks to break the habit of smoking, then gradually reduce lozenge use over a 4 week period. When daily use is 1 to 2 lozenges, use should be stopped. As data are limited in this age group, the recommended duration of treatment is 12 weeks. If longer treatment is required, advice should be sought from a healthcare professional.

Before a recommendation to extend treatment beyond 12 weeks is made the patient should be reassessed for commitment to quitting, expected benefit of continued treatment and maturity. Treatment should not be extended by more than a further 4 weeks.

Combination treatment

Combination therapy may be needed by some patients who have relapsed in the past or if they experience cravings using single therapy.

If patients have repeatedly relapsed using single therapy they should seek professional advice from their doctor or pharmacist.

NICORETTE® 16hr INVISIPATCH® Patch in combination with Nicorette Lozenge 2mg can be used if breakthrough craving is experiences or if there is difficulty in controlling cravings for cigarettes. In people who have been unable to quit smoking using single NRT product, the combination is more effective than either product alone, increasing the patient's chances of successfully quitting.

The treatment involves the addition of NICORETTE® Lozenge 2mg to the patch. The NICORETTE® 16hr INVISIPATCH® patch should be applied daily to an intact area of the skin upon waking and removed at bedtime, and the NICORETTE® Lozenge 2mgshould be used as required when cravings occur.

For heavier smokers (greater than 15 cigarettes a day): use one 25mg/16hr patch/day for 12 weeks plus the 2mg lozenge (at least 4 lozenges; usual dose 5-6 lozenges; maximum 12/day). After the initial 12 weeks treatment period, weaning may be done by either:

- using the 15mg/16hr patch for 2 weeks, followed by the 10mg/16hr patch for 2 weeks, while maintaining the number of 2mg lozenges that have been routinely used; then gradually reducing the number of lozenges once the patch is no longer used; or
- stopping use of the 25mg/16hr patch, and then gradually reducing the number of 2mg lozenges.

For lighter smokers (less than 15 cigarettes a day): use one 15mg/16hr patch/day for 12 weeks plus the 2mg lozenge (at least 4 lozenges; usual dose 5-6 lozenges; maximum 12/day). After the initial 12 weeks treatment period, weaning may be done by either:

- using the 10mg/16hr patch for 4 weeks, while maintaining the number of 2mg lozenges that have been routinely used; then gradually reducing the number of lozenges once the patch is no longer used; or
- stopping use of the 15mg/16hr patch, and then gradually reducing the number of 2mg lozenges.

The NICORETTE® 16hr INVISIPATCH® patch should not be used with NICORETTE® Lozenge 4mg.

Smoking Reduction (Reducing to stop)

The smoker should use NICORETTE® Lozenge between smoking episodes in order to prolong intervals between cigarettes, with the aim of reducing smoking as much as possible. Not more than 15 lozenges should be used in one day.

If the smoker has not achieved a reduction in the number of cigarettes per day after 6 weeks, he or she should consult a healthcare professional. This six-week time period is given to the smoker to allow them to familiarise themselves with NICORETTE® Lozenge and to deal with craving symptoms while they attempt to reduce their smoking.

Smokers who do reduce their smoking with NICORETTE® Lozenge should make a cessation attempt as soon as they feel ready, but not later than 6 months after they start using NICORETTE® Lozenge.

When making a cessation attempt, the smoking cessation instructions, above, can be followed.

If the smoker has not made a cessation attempt within 9 months of commencing treatment he or she should consult a healthcare professional.

4.3 CONTRAINDICATIONS

NICORETTE® Lozenge should not be administered to non-tobacco users or patients with known hypersensitivity to nicotine or any component of the lozenge.

Use in children

NICORETTE® Lozenge should not be administered to children under 12 years of age.

4.4 SPECIAL WARNINGS AND PRECAUTIONS FOR USE

Any risks that may be associated with NRT are substantially outweighed by the well established dangers of continued smoking.

Underlying cardiovascular disease

In stable cardiovascular disease NICORETTE® Lozenge presents a lesser hazard than continuing to smoke. However dependent smokers currently hospitalised as a result of myocardial infarction, severe dysrhythmia or cerebrovascular accident (CVA) and who are considered to be haemodynamically unstable should be encouraged to stop smoking with non- pharmacological interventions. If this fails, NICORETTE® Lozenge may be considered, but as data on safety in this patient group are limited, initiation should only be under medical supervision.

Diabetes mellitus

Patients with diabetes mellitus should be advised to monitor their blood sugar levels more closely than usual when NRT is initiated as catecholamines released by nicotine can affect carbohydrate metabolism.

GI disease

Swallowed nicotine may exacerbate symptoms in patients suffering from oesophagitis, gastritis or peptic ulcers and oral NRT preparations should be used with caution in these conditions.

NICORETTE® Lozenge should be avoided if oral or pharyngeal inflammation is present.

Use in renal impairment

NICORETTE® Lozenge should be used with caution in patients with severe renal impairment as the clearance of nicotine or its metabolites may be decreased with the potential for increased adverse effects.

Use in hepatic impairment

NICORETTE® Lozenge should be used with caution in patients with moderate to severe hepatic impairment as the clearance of nicotine or its metabolites may be decreased with the potential for increased adverse effects.

Phaeochromocytoma and uncontrolled hyperthyroidism

Nicotine, from both NRT and smoking, causes the release of catecholamines from the adrenal medulla. Therefore, NICORETTE® Lozenge should be used with caution in patients with uncontrolled hyperthyroidism or phaeochromocytoma.

Epilepsy and seizures

Caution should be exercised in patients with a history of epilepsy or seizures during introduction of nicotine replacement therapy. Tobacco smoke contains substances – including nicotine – which act on brain receptors, and the changes in intake of these when switching from smoked tobacco to nicotine replacement therapy during quitting may affect seizure threshold.

Allergic reactions

NICORETTE® Lozenge should be used with caution in patients with susceptibility to angioedema and urticaria.

Transferred dependence

Transferred dependence is rare and is both less harmful and easier to break than smoking dependence.

Danger in small children

Doses of nicotine tolerated by adult and adolescent smokers can produce severe toxicity in small children that may be fatal. Products containing nicotine should not be left where they may be misused, handled or ingested by children.

Use in the elderly

A minor reduction in total clearance of nicotine has been demonstrated in healthy elderly patients, however, not justifying an adjustment of dosage.

Paediatric use

NICORETTE® Lozenge should not be administered to children under 12 years of age.

For use in adolescents (12-18 years), see section 4.2 Dose and Method of Administration.

Continued smoking while using NRT

NICORETTE® Lozenge can safely be used while smoking. The adverse event profile (Incidence and severity of events) of intermittent dosing NRT products in studies to reduce smoking did not differ markedly from that in smoking cessation studies. Intermittent use of intermittent dosing NRT products and cigarettes does not appear to produce more side effects than use of NRT alone. Most regular smokers are adept at self-titration of their nicotine intake in order to maintain their plasma nicotine levels within a narrow range.

Lozenges can represent a choking hazard

Keep out of reach of children. NICORETTE® Lozenge should be used with caution in patients with aspiration and swallowing problems.

Effects on laboratory tests

No data available.

4.5 INTERACTION WITH OTHER MEDICINES AND OTHER FORMS OF INTERACTIONS

Interactions with other Medicines

No clinically relevant interactions between nicotine replacement therapy and other drugs has definitely been established. However nicotine may possibly enhance the haemodynamic effects of adenosine i.e. increase in blood pressure and heart rate and also increase pain response (angina-pectoris type chest pain) provoked by adenosine administration.

Stopping smoking

Polycyclic aromatic hydrocarbons in tobacco smoke induce the metabolism of drugs metabolised by CYP 1A2 (and possibly by CYP 1A1). When a smoker stops smoking, this may result in slower metabolism and a consequent rise in blood levels of such drugs. This is of potential clinical importance for products with a narrow therapeutic window, e.g., theophylline, clozapine and ropinirole.

The plasma concentration of other drugs metabolised in part by CYP1A2, for example imipramine, olanzapine, clomipramine, fluvoxamine and caffeine may also increase on cessation of smoking, although data to support this are lacking and the possible clinical significance of this effect is unknown.

Other reported effects of smoking include reduced analgesic efficacy of propoxyphene, reduced diuretic response to frusemide and altered pharmacological response to propanolol, as well as altered rates of ulcer healing with H_2 – antagonists. Both smoking and nicotine can increase levels of circulating cortisol and catecholamines.

Limited data indicate that the metabolism of flecainide and pentazocine may also be induced by smoking.

4.6 FERTILITY, PREGNANCY AND LACTATION

Effects on fertility

Studies have shown a decrease of litter size in rats treated with nicotine during the time of fertilisation.

Use in Pregnancy: Category D

Nicotine is harmful to the foetus. The harmful effects of cigarette smoking on maternal and foetal health are clearly established. Short-term exposure during the first trimester is unlikely to cause a hazard to the foetus.

NRT is not contraindicated in pregnancy. The decision to use NRT should be made on a risk- benefit assessment as early on in the pregnancy as possible with the aim of discontinuing use as soon as possible.

Smoking during pregnancy is associated with risks such as intra-uterine growth retardation, premature birth or stillbirth. Stopping smoking is the single most effective intervention for improving the health of both pregnant smoker and her baby. The earlier abstinence is achieved the better.

Ideally 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.

Nicotine passes to the foetus affecting breathing movements and has a dose-dependent effect on placental/fetal circulation. However the risk to the foetus is lower with NRT than that expected with tobacco smoking, due to lower maximal plasma nicotine concentration and no additional exposure to polycyclic hydrocarbons and carbon monoxide.

Intermittent dosing products may be preferable as these usually provide a lower daily dose of nicotine than patches. However, patches may be preferred if the woman is suffering from nausea during pregnancy. If patches are used they should be removed before going to bed.

Use in Lactation

NRT is not contraindicated in lactation. Nicotine from smoking and NRT is found in breast milk. However the amount of nicotine the infant is exposed to is relatively small and less hazardous than the second-hand smoke they would otherwise be exposed to.

Using intermittent dose NRT preparations, such as NICORETTE® Chewing Gums, Inhalator, Lozenges or Mouth Spray may minimize the amount of nicotine in the breast milk as the time between administrations of NRT and feeding can be more easily prolonged. Women should breastfeed just before using the product.

4.7 EFFECTS ON ABILITY TO DRIVE AND USE MACHINES

The effects of this medicine on a person's ability to drive and use machines were not assessed as part of its registration.

4.8 ADVERSE EFFECTS (UNDESIRABLE EFFECTS)

NICORETTE® Lozenge may cause adverse reactions similar to those associated with nicotine administered by other means and are mainly dose-dependent.

Most of the undesirable effects reported by the patients occur during the first 3-4 weeks after start of treatment. Users may in the beginning of the treatment experience irritation in the mouth and throat.

Some symptoms, such as depression, irritability, anxiety, increased appetite, insomnia, dizziness, headache, sleep disturbance, increased coughing or a cold may be related to withdrawal symptoms associated with abstinence from smoking. Increased frequency of aphthous ulcer may occur after abstinence from smoking. The causality is unclear.

Clinical Trial Data

The safety of nicotine from clinical trial data is based on data on a meta-analysis of randomized clinical trials (RCTs) for the treatment of smoking cessation. Adverse Drug Reactions (ADRs) with oromucosal formulations identified from clinical trials are presented below in Table 1.

Table 1. ADRs Reported with a Frequency ≥1% Identified from Meta-analysis of Clinical Trial Data with Nicotine Oromucosal Formulations

System Organ Class **Preferred Term**	Active N = 3914(%)	Placebo N = 2819 (%)
Gastrointestinal Disorders		
Abdominal Pain	1.8	1.2
Dry Mouth	3.2	2.7
Dyspepsia	6.1	3.3
Flatulence	1.8	1.4
Nausea[a]	10.4	5.8
Salivary hypersecretion	2.6	1.0
Stomatitis	2.6	2.0
Vomiting[a]	2.7	1.2

General Disorders and Administration Site Conditions		
Fatigue[a]	1.0	0.6
*Burning sensation**	1.0	0.5
Immune System Disorders		
Hypersensitivity[a]	1.4	1.22
Nervous System Disorders		
Headache[a#]	11.5	13.0
Paraesthesia[a]*	1.3	0.8
Dysgeusia	3.2	2.8
Respiratory, Thoracic and Mediastinal Disorders		
*Cough***	9.3	10.7
*Hiccups****	16.4	2.3
*Throat irritation***	11.8	4.4

[a] Systemic effects
* At the application site
** Higher frequency observed in clinical studies with inhaler formulation
*** Higher frequency observed in clinical studies with mouth spray formulation
[#] Although the frequency in the active group is less than that of the placebo group, the frequency in the specific formulation in which the PT was identified as a systemic ADR was greater in the active group than the placebo group.

Post Marketing Data

ADRs first identified during post-marketing experience with nicotine are presented in Table 2. Frequencies are provided according to the following convention:

Very common	≥1/10
Common	≥1/100 and < 1/10
Uncommon	≥1/1,000 and <1/100
Rare	≥1/10,000, <1/1,000
Very rare	<1/10,000
Not known	(cannot be estimated from the available data)

Table 2. ADRs Identified During Post-Marketing Experience with Nicotine Oromucosal Formulations with Frequency Category Estimated from Clinical Trials

System Organ Class **Frequency category**	**Preferred Term**
Cardiac Disorders	
Uncommon	*Palpitations***
Uncommon	*Tachycardia***
Eye Disorders	
Not known	*Blurred vision*
Not known	*Lacrimation increased*
Gastrointestinal Disorders	
Common	*Diarrhoea*[#]
Not known	*Dry Throat*
Rare	*Dysphagia*
Uncommon	*Eructation*
Not known	*Gastrointestinal discomfort***
Uncommon	*Glossitis*
Rare	*Hypoaesthesia oral*[#]

Uncommon	*Oral mucosal blistering and exfoliation*
Not known	*Lip pain*
Uncommon	*Paraesthesia oral*[#]
Rare	*Retching*
General Disorders and Administration site Conditions	
Uncommon	*Asthenia***
Uncommon	*Chest discomfort and pain***
Uncommon	*Malaise***
Immune System Disorders	
Not known	*Anaphylactic reaction***
Musculoskeletal and Connective Tissue Disorders	
Not known	*Muscle tightness**
Not known	*Pain in jaw**
Nervous System Disorders	
Not known	*Seizure***
Psychiatric Disorders	*Abnormal dream**,****
Uncommon	
Respiratory, Thoracic and Mediastinal Disorders	
Uncommon	*Dyspnoea***
Uncommon	*Bronchospasm*
Uncommon	*Dysphonia*
Uncommon	*Nasal congestion*
Uncommon	*Oropharyngeal pain*
Uncommon	*Sneezing*
Uncommon	*Throat tightness*
Skin and Subcutaneous Tissue Disorders	
Not known	*Angioedema***
Not known	*Erythema***
Uncommon	*Hyperhidrosis***
Uncommon	*Pruritus***
Uncommon	*Rash***
Uncommon	*Urticaria***
Vascular Disorders	
Uncommon	*Flushing***
Uncommon	*Hypertension***

* Tightness of jaw and pain in jaw with nicotine gum formulation
** Systemic effects
*** Systemic effect, identified only for formulations administered during night
[#] Reported the same or less frequently than placebo

Reporting Suspected Adverse Events

Reporting suspected adverse reactions after registration of the medicinal product is important. It allows continued monitoring of the benefit-risk balance of the medicinal product.

Healthcare professionals are asked to report any suspected adverse reactions at: https://www.tga.gov.au/reporting-problems.

4.9 OVERDOSE

Excessive use of nicotine from either NRT and/or smoking might cause symptoms of an overdose. The risk of poisoning as a result of swallowing the lozenge is very small, as absorption in the absence of sucking is slow and incomplete.

Symptoms of overdosage are those of acute nicotine poisoning and include nausea, salivation, vomiting, abdominal pain, diarrhoea, sweating, headache, dizziness, disturbed hearing and marked weakness. At high doses, these symptoms may be followed by hypotension, weak and irregular pulse, breathing difficulties, prostration, circulatory collapse and general convulsions.

Overdosage with nicotine can occur if the patient has a very low pre-treatment nicotine intake or uses other forms of nicotine. The acute minimum lethal oral dose of nicotine in non- smokers is believed to be 40-60 mg.

Doses of nicotine that are tolerated by adult smokers during treatment may produce severe symptoms of poisoning in small children and may prove fatal. The lethal dose of nicotine in a small child is approximately 10-15 mg. Suspected nicotine poisoning in a child should be considered a medical emergency and treated immediately.

Management of overdose

In the event of overdose or poisoning activated charcoal should be given as soon as possible.

The administration of nicotine should be stopped immediately and the patient should be treated symptomatically. Activated charcoal reduces gastrointestinal absorption of nicotine.

For information on the management of overdose, contact the Poison Information Centre on 13 11 26 (Australia).

5 PHARMACOLOGICAL PROPERTIES

5.1 PHARMACODYNAMIC PROPERTIES

Mechanism of action

Nicotine is a natural alkaloid which has ganglion stimulating properties and produces a wide range of pharmacological actions.

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.

Clinical trials

NICORETTE® Lozenge is a treatment-aid in smoking cessation. Clinical studies have shown that nicotine replacement from nicotine containing products can help people give up smoking by relief of abstinence symptoms associated with smoking cessation.

Abrupt cessation of the use of tobacco-containing products following a prolonged period of daily use results in a characteristic withdrawal syndrome that includes four or more of the following: dysphoria or depressed mood; insomnia; irritability; frustration or anger; anxiety; difficulty concentrating, restlessness or impatience; decreased heart rate; and increased appetite or weight gain. Nicotine craving, which is recognised as a clinically relevant symptom, is also an important element in nicotine withdrawal.

Clinical studies have shown that nicotine replacement products can help smokers abstain from smoking by relieving these withdrawal symptoms.

Cessation rates for reference Nicotine Lozenges from clinical studies have been reported as follows:

	Nicotine Lozenge 2 mg		Nicotine Lozenge 4 mg	
Treatment duration at	Active n=459	Placebo n=458	Active n=450	Placebo n=451
6-week	46.0%	29.7%	48.7%	20.8%
3-month	34.4%	21.6%	35.3%	14.0%
6-month	24.2%	14.4%	23.6%	10.2%

After administration of Nicorette Lozenge the majority of subjects in a bioequivalence study experienced craving relief (i.e. relief in urges to smoke) from 5 minutes onwards.

5.2 PHARMACOKINETIC PROPERTIES

Nicorette Lozenge completely dissolves in the oral cavity, and the entire amount of nicotine contained in the lozenge becomes available for buccal absorption or ingestion (swallowing). Complete dissolution of Nicorette Lozenge is typically achieved in 16-19 minutes. Concurrent consumption of liquids which lower pH in the mouth, such as coffee, juice and carbonated drinks, can reduce the absorption of nicotine. The peak plasma concentration of nicotine achieved after a single dose is approximately 5 ng/ml for Nicorette Lozenge 2 mg (reached after about 40 minutes) and approximately 8 ng/ml for Nicorette Lozenge 4 mg (reached after about 50 minutes). AUC_{∞} after one single dose of Nicorette 2 mg is approximately 16 ng/mLxh after one single dose of Nicorette 4 mg, respectively. The systemic availability of swallowed nicotine is lower due to first pass metabolism. Ingestion of Nicorette Cooldrops Lozenge not following dosing instructions (e.g. chewed and either retained in the mouth and then swallowed, or swallowed immediately) will result in slower and reduced absorption of nicotine.

The volume of distribution following IV administration of nicotine is about 2 to 3 L/kg and the elimination half-life approximately 2 to 3 hours. The major eliminating organ is the liver, and average plasma clearance is about 70 L/hour. The kidney and lung also metabolise nicotine. More than 20 metabolites of nicotine have been identified, all of which are believed to be less active than the parent compound.

The primary metabolite of nicotine in plasma, cotinine, has an elimination half-life of 15 to 20 hours and concentrations that exceed nicotine by 10-fold.

The primary urinary metabolites are cotinine (15% of the dose) and trans-3-hydroxy-cotinine (45% of the dose). About 10% of nicotine is excreted unchanged in the urine. As much as 30% of nicotine may be excreted unchanged in the urine with high flow rates and acidification of the urine below pH 5.

Plasma protein binding of nicotine is less than 5%. Therefore, changes in nicotine binding from use of concomitant drugs or alterations of plasma proteins by disease states would not be expected to have significant effects on nicotine kinetics.

Progressive severity of renal impairment is associated with decreased total clearance of nicotine. Raised nicotine levels have been seen in smoking patients undergoing hemodialysis. The pharmacokinetics of nicotine is unaffected in cirrhotic patients with mild liver impairment (Child-Pugh score 5) and decreased in cirrhotic patients with moderate liver impairment (Child-Pugh score 7). Raised nicotine levels have been seen in smoking patients undergoing haemodialysis.

5.3 PRECLINICAL SAFETY DATA

Genotoxicity

Literature reports indicate that nicotine is neither an initiator nor a tumour promoter in mice.

Neither nicotine nor cotinine was mutagenic in the Ames Salmonella test.

Carcinogenicity

There is inconclusive evidence to suggest that cotinine, an oxidised metabolite of nicotine, may be carcinogenic in rats.

6 PHARMACEUTICAL PARTICULARS

6.1 LIST OF EXCIPIENTS

NICORETTE® Cooldrops Lozenge in addition to the active contains: mannitol, xanthan gum, anhydrous sodium carbonate, sucralose, acesulfame potassium, magnesium stearate, hypromellose, titanium dioxide, winterfresh flavour, polysorbate 80 and Sepifilm gloss.

NICORETTE® Fruitdrops Lozenge in addition to the active contains: mannitol, xanthan gum, anhydrous sodium carbonate, sucralose, acesulfame potassium, magnesium stearate, hypromellose, titanium dioxide, tutti frutti flavour, polysorbate 80 and Sepifilm gloss.

6.2 INCOMPATIBILITIES

Incompatibilities were either not assessed or not identified as part of the registration of this medicine.

6.3 SHELF LIFE

36 months

6.4 SPECIAL PRECAUTIONS FOR STORAGE

Store below 25°C

6.5 NATURE AND CONTENTS OF CONTAINER

NICORETTE® Cooldrops Lozenge 2 mg: polypropylene flip-pack dispenser containing 20 lozenges, in single packs (20 lozenges), packs of 4 dispensers (80 lozenges), packs of 6 dispensers (120 lozenges) and packs of 8 dispensers (160 lozenges).

NICORETTE® Cooldrops Lozenge 4 mg: polypropylene flip-pack dispenser containing 20 lozenges, in single packs (20 lozenges), packs of 4 dispensers (80 lozenges), packs of 6 dispensers (120 lozenges) and packs of 8 dispensers (160 lozenges).
NICORETTE® Fruitdrops Lozenge 2 mg: polypropylene flip-pack dispenser containing 20 lozenges, in single packs (20 lozenges) and packs of 4 dispensers (80 lozenges).

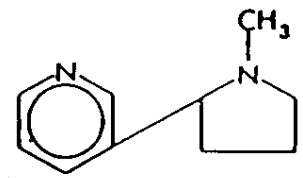
NICORETTE® Fruitdrops Lozenge 4 mg: polypropylene flip-pack dispenser containing 20 lozenges, in single packs (20 lozenges) and packs of 4 dispensers (80 lozenges).

6.6 SPECIAL PRECAUTIONS FOR DISPOSAL

In Australia, any unused medicine or waste material should be disposed of in accordance with local requirements.

6.7 PHYSIOCHEMICAL PROPERTIES

Chemical Structure



CAS number
54-11-5

7 MEDICINE SCHEDULE (POISONS STANDARD)

Unscheduled

8 SPONSOR

Johnson & Johnson Pacific
45 Jones Street
Ultimo NSW 2007
® Registered trademark

9 DATE OF FIRST APPROVAL

NICORETTE® Cooldrops Lozenge 2 mg: 24 January 2013
NICORETTE® Cooldrops Lozenge 4 mg: 24 January 2013
NICORETTE® Fruitdrops Lozenge 2 mg: 03 November 2017
NICORETTE® Fruitdrops Lozenge 4 mg: 03 November 2017

10 DATE OF REVISION

28 April 2023

Summary table of changes

Section changed	Summary of new information
All	Update to new PI format. Addition of more restrictive safety-related information to section 4.8.
4.4, 4.8	Addition of safety-related information on epilepsy and seizures, and potential choking hazard.