AUSTRALIAN PRODUCT INFORMATION

NICABATE GUM (NICOTINE) CHEWING GUM

1 NAME OF THE MEDICINE

Nicotine

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active ingredient: *Nicotine*

Nicotine is 3-[(2S)-1-methylpyrolidin-2-yl]pyridine and is the major pharmacologically active alkaloid of tobacco. The free alkaloid is absorbed rapidly through the skin and respiratory tract.

Nicotine 2 mg coated chewing gum

Nicotine 4 mg coated chewing gum

Excipients: For the full list of excipients, see section 6.1 List of Excipients.

3 PHARMACEUTICAL FORM

Off-white rectangular pillow-shaped coated chewing gum and is approximately 20 x 12 mm.

4 CLINICAL PARTICULARS

4.1 THERAPEUTIC INDICATIONS

For the relief of nicotine withdrawal symptoms including nicotine cravings associated with smoking cessation. It may also 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. If possible, when stopping smoking, it should be used in conjunction with a behavioural support programme as this normally improves the success rate.

4.2 DOSE AND METHOD OF ADMINISTRATION

Adults (18 years and over including the elderly)

Nicabate gum 2 mg is suitable for smokers who smoke fewer than 20 cigarettes a day.

Nicabate gum 4 mg is suitable for smokers who smoke more than 20 cigarettes a day.

Users should make every effort to stop smoking completely during treatment with Nicabate gum.

Behavioural therapy, advice and support will normally improve the success rate.

Nicabate gums should be chewed as directed whenever there is an urge to smoke, to maintain complete abstinence from smoking.

Users should follow the schedule of treatment in Table 1 below:

Table 1

STEP 1	**STEP 2**	**STEP 3**	
Initial treatment period. 12 weeks	Step down treatment period. 2 weeks	Step off treatment period 2 weeks	
Chew 1 piece whenever there is an urge to smoke. Use 8 – 12 pieces/day of the 2 mg strength or 8-10 pieces/day of the 4 mg strength.	Gradually reduce gum use to 4 - 6 pieces/day.	Use 1 – 3 pieces of gum/day. Reduce to zero over 2 weeks.	To help you stay smoke free, take 1 piece of gum when you are strongly tempted to smoke.

The user dose and duration of treatment is individual and dependent on how much nicotine you need to reduce the withdrawal symptoms. Clinical experience has shown that the treatment should last for at least 3 months. When daily use is 1-2 gums, use should be stopped. Any spare gums should be retained as cravings may suddenly return.

Users should not use more than one piece of gum at a time and should not exceed 20 pieces/day of the 2 mg strength or 10 pieces/day of the 4 mg strength.

Users should not use more than 1 gum per hour.

Absorption of nicotine is through the buccal mucosa and any nicotine that is swallowed is destroyed by the liver.

Directions for Use

Patients should be directed to chew each piece of gum slowly until the taste becomes strong (about 1 minute) then stop and rest the gum against the cheek. Once the taste fades, the gum should be chewed a few times until the taste gets strong then rested again against the cheek. This sequence should be repeated for about 30 minutes until the gum has lost its strength.

Acidic beverages e.g. coffee or soft drink interfere with the buccal absorption of nicotine.

The user should not eat or drink while using the chewing-gum. Drinks that lower the pH in the mouth, e.g. coffee, fruit juice or sodas, may reduce the absorption of nicotine from the oral cavity. To achieve the maximum absorption of nicotine, these drinks should be avoided up to 15 minutes prior to using the chewing gum.

Those who use the gum beyond 9 months are recommended to seek additional help and advice from a healthcare professional who may consider alternate quit strategies such as combination therapy.

Children and adolescents

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

Data are limited in relation to the value of NRT use in young people where the demand for cessation products and the motivation to quit is low. Nevertheless NRT is safe in this group. NRT should only be used by adolescents in conjunction with a counselling programme. Counselling is needed in this age group because NRT is likely to be ineffective in the absence of counselling.

Adolescents (12-17 years) should follow the schedule of treatment for adults in the table above for steps 1, 2 and 3 but, as data are limited, duration of NRT in this age group is restricted to 10 weeks. If longer treatment is required, advice from a healthcare professional should be sought who can then reassess the patient for their commitment to quitting and the benefits of continued treatment. If treatment is continued, it should not be extended for more than another four weeks.

Adolescents should not quit with a Combination NRT Regimen.

Nicabate gum is not recommended for use in children under 12 years of age.

Combination therapy

In some instances, it may be beneficial to utilize more than one form of NRT concurrently. For example, combination therapy could be used by smokers who have relapsed with NRT monotherapy in the past, who experience breakthrough cravings or have difficulty controlling cravings for cigarettes using single therapy. This would allow users to identify the combination most appropriate for their individual quit attempt. If required, Nicabate gum 2 mg, or Nicabate 2 mg Mini Lozenges may be combined with Nicabate 21 mg patches. Nicabate gum 4 mg and/or Nicabate 4 mg Mini Lozenges should not be used with Nicabate patches.

When using Nicabate 21 mg patches in addition to Nicabate 2 mg gums or 2 mg Mini Lozenges, it is recommended that a minimum of 4 pieces of gum /4 Mini Lozenges are used daily. Most

people will use 4-5 pieces. The maximum number of gums or Mini lozenges used in conjunction with the patch is 12 pieces per day.

Combination treatment should be used for 12 weeks after which weaning may be initiated. If required, weaning may be done by either:

1 Using Nicabate 14 mg patch for 2 weeks and then Nicabate 7 mg patch for 2 weeks while maintaining the number of pieces of 2 mg gum or 2 mg Mini Lozenges that have been routinely used. Then, when a patch is no longer used, the number of pieces of gum or 2 mg Mini Lozenges can be gradually reduced. OR

2 Stopping use of Nicabate 21 mg patch and then gradually reducing the number of pieces of 2 mg gum or 2 mg Mini Lozenges that are being used.

Users should stop smoking completely during treatment with Nicabate 2 mg gum or 2 mg Mini Lozenges in combination with Nicabate 21 mg patches.

Harm Reduction

Gradual cessation of smoking

Reduce to quit

For smokers who are unwilling or unable to quit abruptly. Use a piece of gum whenever there is a strong urge to smoke in order to reduce the number of cigarettes smoked as far as possible and to refrain from smoking as long as possible. The number of pieces of gum a day is variable and depends on the patient's needs. Nonetheless it should not exceed 20 pieces per day of the 2 mg strength or 10 pieces per day of the 4 mg strength.

Users should not use more than 1 gum per hour.

If a reduction in cigarette consumption has not been achieved after 6 weeks of treatment, a healthcare professional should be consulted. Reduced tobacco consumption may help to lead to complete cessation of smoking. This should be attempted as soon as possible. When the number of cigarettes has been reduced to a level from which the user feels able to quit completely, then start on the schedule for "abrupt cessation' as given above.

If an attempt to stop smoking completely has not been started within 6 months after the beginning of treatment, it is recommended to consult a healthcare professional.

4.3 CONTRAINDICATIONS

Nicabate should not be used by:

- Non-smokers
- Children under 12 years of age
- Those with hypersensitivity to nicotine or any of the excipients

4.4 SPECIAL WARNINGS AND PRECAUTIONS FOR USE

The risks associated with the use of NRT (Nicotine replacement therapy) are substantially outweighed in virtually all circumstances by the well-established dangers of continued smoking.

Patients hospitalised for myocardial infarction, severe dysrhythmia or CVA

Patients hospitalised for myocardial infarction, severe dysrhythmia or CVA (cerebrovascular accident) who are considered to be haemodynamically unstable should be encouraged to stop smoking with non-pharmacological interventions. If this fails, Nicabate gum may be considered, but as data on safety in this patient group are limited, initiation should only be under medical supervision. Once patients are discharged from hospital, they can use NRT on medical advice. If there is a clinically significant increase in cardiovascular or other effects attributable to nicotine, the gums should be reduced or discontinued.

Use with caution in patients with recent or unstable cardiovascular disease. In patients with unstable cardiovascular disease, do not continue NRT if patient continues to smoke.

The combination NRT regimen should not be used in people with known cardiovascular disease without evaluation of the risk/benefit by a health care professional.

Seizures

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

Diabetes mellitis

Blood glucose levels may be more variable when stopping smoking, with or without NRT, so it is important for patients with diabetes mellitus to monitor their blood glucose levels more closely than usual when NRT is initiated as catecholamines released by nicotine can affect carbohydrate metabolism and vasoconstriction may delay/reduce insulin absorption.

Allergic reactions

Susceptibility to angioedema and urticaria. NRT should be used with caution by patients who are susceptible to angioedema and/or urticaria.

Phaeochromocytoma and uncontrolled hyperthyroidism

Use with caution in patients with uncontrolled hyperthyroidism or phaeochromocytoma as nicotine causes release of catecholamines. A risk-benefit assessment should be made by an appropriate healthcare professional.

GI disease

Swallowed nicotine may exacerbate symptoms in patients suffering from active oesophagitis, oral or pharyngeal inflammation, gastritis and gastric or peptic ulcers. Oral NRT preparations

should be used with caution in these conditions. Ulcerative stomatitis has been reported. A risk-benefit assessment should be made by an appropriate healthcare professional.

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.

Transferred dependence

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

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 a 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, tacrine, clozapine and ropinirole. The plasma concentration of other medicinal products metabolised in part by CYP1A2 e.g. imipramine, olanzapine, clomipramine and fluvoxamine may also increase on cessation of smoking, although data to support this are lacking and the possible clinical significance of this effect for these drugs is unknown. Limited data indicate that the metabolism of flecainide and pentazocine may also be induced by smoking.

Sorbitol (E420)

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

Butylated hydroxytoluene (E321)

May cause irritation of mucous membranes.

Sodium

Nicabate Gum contains 10.5 mg (2 mg gum) or 14.0 mg (4 mg gum) of sodium per piece of gum. To be taken into consideration by patients on a controlled sodium diet.

During a quit attempt, users should not interchange nicotine gums with nicotine lozenges since pharmacokinetic data indicate a higher availability of nicotine from some nicotine lozenges in comparison to the gum.

Dental

Smokers who wear dentures or who have temporomandibular joint disease may experience difficulty in chewing Nicabate gum.
Nicotine gum may loosen fillings or dental implants.

Oral

Use of Nicabate gum may exacerbate oral inflammation.

Use in hepatic impairment

Use 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. A risk-benefit assessment should be made by an appropriate healthcare professional.

Use in renal impairment

Use 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. A risk-benefit assessment should be made by an appropriate healthcare professional.

Use in the elderly

No data available.

Paediatric use

Do not use in children under 12 years of age.

Effects on laboratory tests

No data available.

4.5 INTERACTIONS WITH OTHER MEDICINES AND OTHER FORMS OF INTERACTIONS

No clinically relevant interactions between nicotine replacement therapy and other drugs have 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 (anginapectoris type chest pain) provoked by adenosine administration, (see 'Special warnings and precautions for use').

Smoking cessation, with or without nicotine replacement, may alter the individual's response to concomitant medication and may require adjustment of dose.

Polycyclic aromatic hydrocarbons in tobacco smoke induce the metabolism of drugs metabolised by CYP 1A2 (and possibly by CYP 1A1). When a smoker stops this may result in a slower metabolism and a consequent rise in blood levels of such drugs.

The following drugs may require adjustment in dose at cessation of smoking:

Caffeine, theophylline, imipramine, pentazocine, tacrine, clomipramine, insulin, clozapine, olanzapine and fluvoxamine. In particular, anticonvulsants may require special monitoring and/or dosage adjustment.

Other reported effects of smoking include reduced analgesic efficacy of propoxyphene, reduced diuretic response to frusemide and altered pharmacological response to propranolol, as well as altered rates of ulcer healing with H_2 antagonists. Both smoking and nicotine can increase levels of circulating cortisol and catecholamines. Dosages of nifedipine, adrenergic agonists or adrenergic blocking agents may need to be adjusted.

Insulin dependent diabetes – smoking cessation may lead to an increase in subcutaneous insulin absorption.

4.6 FERTILITY, PREGNANCY AND LACTATION

Effects on fertility

In rats and rabbits, implantation can be delayed or inhibited by a reduction DNA synthesis that appears to be caused by nicotine. Studies have shown a decrease in litter size in rats treated with nicotine during gestation.

Use in pregnancy – Pregnancy Category D

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 should only be used on the advice of a health care professional. Nicotine is harmful to the foetus. However, the risk of using NRT to the foetus is lower than that expected with tobacco smoking, due to lower maximal plasma nicotine concentration and no additional exposure to polycyclic hydrocarbons and carbon monoxide.

However, as nicotine passes to the foetus affecting breathing movements and has a dose dependent effect on placental/foetal circulation, the decision to use NRT should be made as early on in the pregnancy as possible. The aim should be to use NRT for only 2-3 months.

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.

Use in lactation.

Nicotine from smoking and NRT is found in breast milk. However the amount of nicotine the infant is exposed to from NRT is relatively small and less hazardous than the second-hand smoke they would otherwise be exposed to.
Ideally smoking cessation during lactation should be achieved without NRT. However for women unable to quit on their own, NRT may be recommended to assist a quit attempt.
Using intermittent dose NRT preparations, compared with patches, may minimize the amount of nicotine in the breast milk as the time between administrations of NRT and feeding can be made as long as possible. Women should try to breastfeed just before they take the product.

4.7 EFFECTS ON ABILITY TO DRIVE AND USE MACHINES

Nicabate Gums have no or negligible influence on the ability to drive and use machines. However, users of nicotine replacement products should be aware that smoking cessation can cause behavioural changes.

4.8 ADVERSE EFFECTS (UNDESIRABLE EFFECTS)

Nicotine lozenges / gum / patches can cause adverse reactions similar to those associated with nicotine from tobacco. Many of the observed adverse reactions are consistent with the pharmacological effects of nicotine, which are dose dependent.

At recommended doses Nicabate gum has not been found to cause any serious adverse effects. Excessive consumption of Nicabate extra fresh gum by those who have not been in the habit of inhaling tobacco smoke, could possibly lead to nausea, faintness or headaches.

Certain symptoms that have been reported such as depression, irritability, anxiety, increased appetite and insomnia may be related to withdrawal symptoms associated with smoking cessation. Subjects quitting smoking by any means could expect to suffer from headache, dizziness, sleep disturbance, increased coughing or a cold.

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) and very rare (<1/10,000), not known (cannot be estimated from the available data).

Table 2

System Organ Class and Frequency	Adverse Reaction/Events
Psychiatric disorders	
Common	Insomnia, irritability
Central and peripheral nervous system disorders	
Common	Dizziness, headache
Uncommon	Lightheadedness, tremor
Gastrointestinal system disorders	
Common	Nausea, gastrointestinal discomfort, sore mouth, vomiting, indigestion, mouth irritation, mouth ulceration, dyspepsia, abdominal pain upper, diarrhoea, dry mouth, constipation, hiccups, flatulence, oral discomfort
Uncommon	Stomatitis
Respiratory, thoracic and mediastinal disorders	
Common	Hiccups, sore throat, pharyngitism cough, pharyngolaryngeal pain
Uncommon	Dyspnoea
Musculoskeletal and connective tissue disorders	
Common	Jaw pain
Cardiac disorders	
Uncommon	Palpitation, tachycardia
Rare	Atrial fibrillation
Skin and subcutaneous tissue disorders	
Uncommon	Erythema, urticaria, increased sweating
Immune system disorders	
Rare	Allergic reactions such as angio-oedema
Very rare	Anaphylactic reactions
Special senses other, disorders	
Uncommon	Parageusia, metallic taste, taste perversion
General disorders and administration site conditions	
Uncommon	Chest pain, arthralgia, myalgia, malaise

Paediatric population (12-17 years inclusive)

There are no specific adverse event data for this population. However, the frequency, type and severity of adverse reactions in adolescents are expected to be the same as in adults, based upon the pharmacokinetic study demonstrating a similar pharmacokinetic profile in the adolescent age group to adults.

Reporting suspected adverse effects

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 www.tga.gov.au/reporting-problems.

4.9 OVERDOSE

Overdosage can occur if many gums are taken simultaneously or in rapid succession. The consequences of an overdose are most likely to be minimised by the early nausea and vomiting known to occur with excessive nicotine intake. Nicotine is also subject to a significant first-pass metabolism.

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

The minimum lethal dose of nicotine in a non-tolerant man has been estimated to be 40 to 60 mg. Signs and symptoms of an overdose from nicotine gum would be expected to be the same as those of acute nicotine poisoning including pallor, nausea, vomiting, salivation, abdominal pain, diarrhoea, sweating, headache, dizziness, disturbed hearing and vision, tremor, mental confusion and marked weakness. In extreme cases, these symptoms may be followed by hypotension, rapid or weak or irregular pulse, breathing difficulties, respiratory failure, prostration, circulatory collapse and terminal convulsions.

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

All nicotine intake should stop immediately and the patient should be treated symptomatically. Artificial respiration with oxygen should be instituted if necessary. 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.

5 PHARMACOLOGICAL PROPERTIES

5.1 PHARMACODYNAMIC PROPERTIES

Mechanism of action

The pharmacological effects of nicotine are well documented. Those resulting from chewing Nicabate gum are comparatively small. The response at any one time represents a summation of stimulant and depressant actions from direct, reflex and chemical mediator influences on several organs.

The main pharmacological actions are central stimulation and/or depression, transient hyperpnoea, peripheral vasoconstriction (usually associated with a rise in systolic pressure), suppression of appetite and stimulation of peristalsis.

Withdrawal symptoms associated with the abrupt cessation of the use of nicotine include dysphoria, depressed mood, insomnia, irritability, frustration or anger, anxiety, difficulty concentrating, restlessness or impatience, decreased heart rate, increased appetite or weight gain and nicotine craving. These symptoms have been shown in clinical studies to be relieved by nicotine replacement products such as Nicabate gum.

Clinical trials

No data available.

5.2 PHARMACOKINETIC PROPERTIES

Absorption

Nicotine administered in chewing gums is readily absorbed from the buccal mucous membranes. Demonstrable blood levels are obtained within 5 - 7 minutes and reach a maximum about 30 minutes after the start of chewing. Blood levels are roughly proportional to the amount of nicotine chewed and have been shown never to exceed those obtained from smoking cigarettes.

Distribution

As the plasma protein binding of nicotine is low (4.9% - 20%), the volume of distribution of nicotine is large (2.5 l/kg). The distribution of nicotine to tissue is pH dependent, with the highest concentrations of nicotine found in the brain, stomach, kidney and liver. Nicotine crosses the blood-brain barrier, the placenta and is detectable in breast milk.
Mean steady state trough levels of 9-10 ng/mL are achieved during standardised conditions i.e. chewing every four seconds for 30 minutes.
The volume of distribution following IV administration of nicotine is about 2 to 3 L/kg and the half-life approximately 2 hours.

Metabolism

The metabolism of nicotine primarily occurs in the liver, but also in the lung and kidney. More than 20 metabolites of nicotine have been identified all of which are believed to be less active than the parent compound. Nicotine is metabolized primarily to cotinine but is also metabolized to nicotine N'-oxide. Cotinine has a half-life of 15 to 20 hours and its blood levels are 10 times higher than nicotine. Cotinine is further oxidized to trans-3'-hydroxycotinine, which is the most abundant metabolite of nicotine in the urine. Both nicotine and cotinine undergo glucuronidation.

Excretion

The elimination half-life of nicotine is approximately 2 hours (range 1 – 4 hours). Total clearance for nicotine ranges from approximately 62 to 89 l/hr. Non-renal clearance for nicotine is estimated to be about 75% of total clearance. Nicotine and its metabolites are excreted almost exclusively in the urine. The primary urinary metabolites are cotinine (15% of the dose) and trans-3-hydroxy-cotinine (45% of the dose). The renal excretion of unchanged nicotine is highly dependent on urinary pH with greater excretion occurring at acidic pH. About 10% of nicotine is excreted unchanged in the urine. As much as 30% of nicotine may be excreted unchanged 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 alternatives, 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. The pharmacokinetics of nicotine is unaffected in cirrhotic patients with mild liver impairment (Child score 5) and decreased in cirrhotic patients with moderate liver impairment (Child score 7). Raised nicotine levels have been seen in smoking patients undergoing haemodialysis.

There are no differences in nicotine kinetics between men and women.

5.3 PRECLINICAL SAFETY DATA

Genotoxicity

Nicotine and cotinine were not mutagenic in the Ames *Salmonella* test. Nicotine induced repairable DNA damage in an *E.coli* test system. Nicotine was shown to be genotoxic in a test system using Chinese hamster ovary cells.

Carcinogenicity

Nicotine itself does not appear to be a carcinogen in laboratory animals. However, nicotine and its metabolites increased the incidence of tumours in the cheek pouches of hamsters and forestomach of F344 rats, respectively, when given in combination with tumour initiators. One study, which could not be replicated, suggested that cotinine, the primary metabolite of nicotine, may cause lymphoreticular sarcoma in the large intestine in rats.

Studies in male rats have shown that nicotine can decrease testis weight, cause a reversible decrease in Sertoli cell numbers with impairment of spermatogenesis, and result in a variety of changes in the epididymis and vas deferens. However, similar effects have not been reported to occur in humans.

6 PHARMACEUTICAL PARTICULARS

6.1 LIST OF EXCIPIENTS

Gum Base 25048 (incl. 0.09 %w/w Butylated hydroxytoluene (E321), calcium carbonate (E170), sorbitol (E420), glycerol (E422), acesulfame potassium (E950), eucamenthol flavour, mannitol, sodium carbonate anhydrous (E500), carnauba wax (E903), xylitol (E967), levomenthol flavour, optacool flavour, sucralose (E955), talc-purified, titanium dioxide (E171), acacia (E414).

6.2 INCOMPATIBILITIES

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

6.3 SHELF LIFE

In Australia, information on the shelf life can be found on the public summary of the Australian Register of Therapeutic Goods (ARTG). The expiry date can be found on the packaging.

6.4 SPECIAL PRECAUTIONS FOR STORAGE

Store below 25°C.

6.5 NATURE AND CONTENTS OF CONTAINER

Nicabate gum is available in two strengths: 2 mg and 4 mg in PVC/PVDC/Aluminium blister packs of 24, 30, 100, 200 and 300 gums.

Not all pack sizes may be marketed.

All presentations contain information on Nicabate gum and how to use it.

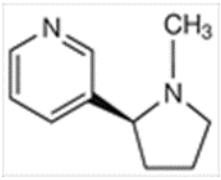
6.6 SPECIAL PRECAUTIONS FOR DISPOSAL

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

6.7 PHYSICOCHEMICAL PROPERTIES

Chemical structure

Nicotine



CAS number 54-11-5

7 MEDICINE SCHEDULE (POISONS STANDARD)

Unscheduled

8 SPONSOR

Haleon

Sydney, NSW, Australia

Telephone: 1800 028 533

Website: www.haleon.com

9 DATE OF FIRST APPROVAL

NICABATE GUM 2 mg

(AUST R 258232) 28 August 2015

NICABATE GUM 4 mg

(AUST R 258233) 28 August 2015

10 DATE OF REVISION

6 SEPTEMBER 2024

SUMMARY TABLE OF CHANGES

Section Changed	Summary of new information
4.2	Combination Therapy: All references of Nicabate Mini Lozenges 1.5 mg have been changed to Nicabate Mini Lozenges 2 mg.
4.4	Patients hospitalised for myocardial infarction, severe dysrhythmia or CVA: Correction of a typo – 'Mini Lozenges' should be 'gums'
8	Sponsor: Change from 'GlaxoSmithKline Consumer Healthcare' to 'Haleon'