DATA SHEET

1. PRODUCT NAME

NICORETTE® QUICKMIST (1mg nicotine/spray, mouth spray)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

NICORETTE® QUICKMIST contains nicotine as the active ingredient. 0.07 ml contains 1 mg nicotine, corresponding to 1mg nicotine/spray dose and is available in 2 flavours: freshmint and cool berry.

Excipients with known effect:

NICORETTE® QUICKMIST also contains alcohol.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Clear to weakly opalescent, colorless to light yellow solution.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

For the treatment of tobacco and nicotine vaping dependence by relieving nicotine craving and withdrawal symptoms thus:

Facilitating smoking and vaping cessation in smokers and vapers motivated to quit. Helping smokers and vapers to temporarily abstain from smoking and vaping.

Facilitating smoking and vaping reduction in smokers and vapers unable or unwilling to quit.

4.2 Dose and method of administration

After priming, the spray nozzle should be pointed as close to the open mouth as possible. The top of the dispenser is then pressed releasing one spray into the mouth, avoiding the lips. The patient should not inhale while spraying to avoid getting spray into the respiratory tract. For best results, do not swallow for a few seconds after spraying. Do not eat or drink when administering the mouth spray.

Children and Adolescents

The safety and efficacy of NICORETTE® QUICKMIST in children and adolescents has not been investigated (see section 5.1).

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

NICORETTE® QUICKMIST should be used in adolescents only under the supervision of a doctor or pharmacist.

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 6 weeks to break the habit of smoking and vaping, and then gradually reduce mouth spray use over a 6 week period. When daily use is 2 to 4 sprays, use should be stopped.

STOPPING IMMEDIATELY PROGRAMME	
During weeks 1-6	1 or 2 sprays should be used when cigarettes/vapes would normally be smoked/vaped or if cravings emerge. Patients should not use more than 2 sprays at a time, 4 sprays per hour for 16 hours, or 64 sprays per day.
During weeks 7-9	Patients should start reducing the number of sprays per day. By the end of week 9 patients should be using HALF the average number of sprays per day that were used in Step I.
During weeks 10-12	Use should be gradually reduced to 2 to 4 sprays per day and then stopped. Use beyond 12 weeks in adolescents is not recommended.

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.

Adults and Elderly

Smoking and Vaping cessation

The following chart lists the recommended usage schedule for NICORETTE® QUICKMIST during full treatment (Step I) and during tapering (Step II and Step III). Up to 4 sprays per hour may be used. No more than 2 sprays per dosing episode should be used and no more than 64 sprays (4 sprays per hour, over 16 hours) in any 24-hour period.

Step I: Weeks 1-6

Use 1 or 2 sprays when cigarettes/ vapes normally would have been smoked/ vaped or if cravings emerge. If after a single spray cravings are not controlled within a few minutes, a second spray should be used. If 2 sprays are required, future doses may be delivered as 2 consecutive sprays.

Most smokers/ vapers will require 1-2 sprays every 30 minutes to 1 hour.

Step II: Weeks 7-9

Start reducing the number of sprays per day. By the end of week 9 patients should be using HALF the average number of sprays per day that was used in Step I.

Step III: Weeks 10-12

Continue reducing the number of sprays per day so that no more than 4 sprays per day during week 12 are used. Treatment should be stopped when the dose is reduced to 2-4 sprays per day.

Example: If an average of 15 cigarettes per day are usually smoked, or a vape is vaped 15 times a day, 1-2 sprays should be used at least 15 times during the day.

To help stay smoke or vape free after Step III, patients may continue to use the spray in situations when they are strongly tempted to smoke or vape. One spray may be used in situations where there is an urge to smoke or vape, with a second spray if one spray does not help within a few minutes. No more than four sprays per day should be used during this period.

Regular use of the mouth spray beyond 6 months is generally not recommended. Some ex-smokers/ vapers may need treatment with the spray longer to avoid returning to smoking/ vaping. Any remaining mouth spray should be retained to be used in the event of sudden cravings.

Smoking and Vaping reduction

Use NICORETTE® QUICKMIST between smoking/ vaping episodes whenever there is an urge to smoke/ vape, to prolong smoke-free/ vape-free intervals and with the intention to reduce your smoking as much as possible. If a reduction in the number of cigarettes/ vapes per day has not been achieved after 6 weeks it should be considered to seek professional advice.

A quit attempt should be made as soon as you feel ready but not later than 6 months after start of treatment. If it is not possible to make a serious quit attempt within 9 months after start of treatment then seek professional advice.

Some ex-smokers/ ex-vapers may need longer treatment with NICORETTE® QUICKMIST to avoid returning to smoking/ vaping. Any spare NICORETTE® QUICKMIST should be retained, as craving may suddenly occur.

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

Advice and support normally improve the success rate.

Temporary abstinence

Use NICORETTE® QUICKMIST during smoke-free/ vape-free periods, for example in smoke-free/ vape-free areas or in other situations when you wish to avoid smoking/ vaping, and there is an urge to smoke/ vape.

Combination treatment – For smokers only

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

The NICORETTE® 16hr INVISIPATCH® patch should be applied daily to an intact area of the skin upon waking and removed at bedtime. After applying the NICORETTE® 16hr INVISIPATCH® Patch, the NICORETTE® QUICKMIST should be used as required when cravings occur.

<u>For heavier smokers (more than 15 cigarettes a day):</u>

One NICORETTE® 25mg/16 hr INVISIPATCH® Patch should be applied daily for 12 weeks. The NICORETTE® QUICKMIST mouth spray should be used as required when breakthrough cravings occur, at a dose of 1 or 2 sprays every 30 – 60 minutes. The maximum number of doses of mouth spray used in conjunction with the NICORETTE® 25 mg/16 hr INVISIPATCH® is 32 sprays per day (two sprays per hour for 16 hours).

After the initial 12 weeks treatment period, weaning may be done by either:

Using the NICORETTE® 15mg/16 hr INVISIPATCH® patch for 2 weeks, followed by the NICORETTE® 10mg/16 hr INVISIPATCH® patch for 2 weeks, while maintaining the number of sprays of mouth spray that have been routinely used; then gradually reducing the number of sprays once the patch is no longer used;

OR

Stopping use of the NICORETTE® 25mg/16 hr INVISIPATCH® patch, and then gradually reducing the sprays from the mouth spray.

<u>For lighter smokers (less than 15 cigarettes a day):</u>

One NICORETTE® 15mg/16 hr INVISIPATCH® patch should be applied daily for 12 weeks. The NICORETTE® QUICKMIST mouth spray should be used as required when breakthrough cravings occur,

at a dose of 1 or 2 sprays every 30 – 60 minutes. The maximum number of doses of mouth spray used in conjunction with the NICORETTE® 15 mg/16 hr INVISIPATCH® is 32 sprays per day (two sprays per hour for 16 hours).

After the initial 12 weeks treatment period, weaning may be done by either:

Using the NICORETTE® 10mg/16 hr INVISIPATCH® patch for 4 weeks, while maintaining the number of sprays of mouth spray that have been routinely used; then gradually reducing the number of sprays once the patch is no longer used;

OR

Stopping use of the NICORETTE® 15 mg/16 hour INVISIPATCH® Patch and then gradually reducing the number of doses of NICORETTE® QUICKMIST® that are being used.

4.3 Contraindications

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

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. The risks of continued vaping are not yet established.

Care should be taken not to spray the eyes whilst administering the mouth spray.

Underlying cardiovascular disease

In stable cardiovascular disease NICORETTE® QuickMist presents a lesser hazard than continuing to smoke. However dependent smokers currently hospitalised as a result of myocardial infarction, severe dysrrhythmia 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® QuickMist 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 reductions in nicotine induced catecholamine release 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® QuickMist should be avoided if oral or pharyngeal inflammation is present.

Use in renal impairment

NICORETTE® QuickMist 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® QuickMist 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® QuickMist 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

Transferred dependance

Transferred dependence can occur but it is both less harmful and easier to break than smoking dependence. Special warnings and precautions for the combination of nicotine mouth spray with nicotine patch are the same as those for each treatment alone.

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

Total clearance of nicotine is reduced in elderly smokers to a variable extent and is considered not supportive of general age-dependent dose adjustments.

Paediatric use

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

Continued smoking while using NRT

NICORETTE® QUICKMIST can be safely used while smoking. The adverse event profile (incidence and severity of events) of intermittent 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 in order to maintain their plasma nicotine levels within a narrow range.

Effects on laboratory tests

No data available.

4.5 Interaction with other medicines and other forms of interaction

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.

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.

4.6 Fertility, pregnancy and lactation

Nicotine passes to the foetus and affects its breathing movements and circulation. The effect on the circulation is dose dependent. Smoking can seriously harm the foetus or infant and should be stopped. Pregnant or breast-feeding smokers should only use NICORETTE® QUICKMIST after consulting a health care professional. The risks for the foetus from NICORETTE® QUICKMIST are not fully known. The benefits of nicotine replacement therapy in pregnant women who cannot abstain without such therapy substantially outweigh the risk of continued smoking.

Nicotine passes into breast milk in small quantities that may affect the infant, even at therapeutic doses. To reduce the exposition to the child the NICORETTE® QUICKMIST should be used just after breast-feeding.

The effects of vaping on your body during pregnancy, breastfeeding, babies and children are not established.

4.7 Effects on ability to drive and use machines

NICORETTE® QUICKMIST has no or negligible influence on the ability to drive and use machines.

4.8 Undesirable effects

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

Patients quitting habitual tobacco use by any means could expect to suffer from an associated nicotine 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, increased appetite or weight gain. These have been observed in those using the mouth spray. In addition to these, other cessation-associated symptoms were seen in those using the mouth spray: Dizziness, presyncopal symptoms, cough, constipation, mouth ulceration, gingival bleeding and nasopharyngitis.

The nicotine withdrawal effects of vaping cessation have not been established, however it is anticipated that many of the effects relating to nicotine withdrawal will be the same as those seen with tobacco smoking cessation.

Local adverse effects of administration are similar to those seen with other orally delivered forms. Irritation in the mouth or throat and hiccups may be experienced during the first few days of treatment, however most patients adapt to this with ongoing use.

Table 1: ADRs Identified from Meta-analysis of Clinical Trials and from Post-Marketing Data with Nicotine Oromucosal Formulations

System Organ Class	Preferred Term	Frequency[§]
Cardiac Disorders	Palpitations[a]	Uncommon
	Tachycardia[a]	Uncommon
Eye Disorders	Blurred vision	Not known
	Lacrimation increased	Not known
Gastrointestinal Disorders	Abdominal pain	Common
	Dry mouth	Common
	Diarrhoea[$]	Common
	Dry throat	Not known
	Dyspepsia	Common
	Dysphagia	Rare
	Eructation	Uncommon
	Gastrointestinal discomfort[a]	Not known
	Glossitis	Uncommon
	Hypoaesthesia oral[$]	Rare
	Flatulence	Common
	Lip pain	Not known
	Nausea[a]	Very common
	Oral mucosal blistering and exfoliation	Uncommon
	Paraesthesia oral[$]	Uncommon

	Retching Salivary hypersecretion Stomatitis Vomiting[a]	Rare Common Common Common
General Disorders and Administration Site Conditions	Asthenia[a] Burning sensation* Chest discomfort and pain Fatigue[a] Malaise[a]	Uncommon Common Uncommon Common Uncommon
Immune System Disorders	Anaphylactic reaction[a] Hypersensitivity[a]	Not known Common
Nervous System Disorders	Seizure[a]	Not known
Musculoskeletal and Connective Tissue Disorders	Muscle tightness* Pain in Jaw Headache[a#] Dysgeusia Paraesthesia[a]	Not known Uncommon Very common Common Common
Psychiatric Disorders	Abnormal dream[a ***]	Uncommon
Respiratory, Thoracic and Mediastinal Disorders	Bronchospasm Cough** Dysphonia Dyspnoea[a] Hiccups Nasal congestion Oropharyngeal pain Sneezing Throat tightness Throat irritation	Uncommon Very common Uncommon Uncommon Very common Uncommon Uncommon Uncommon Uncommon Very common
Skin and Subcutaneous Tissue Disorders	Angioedemaa Erythema[a] Hyperhidrosis[a] Pruritus[a] Rash[a] Urticaria[a]	Not known Not known Uncommon Uncommon Uncommon Uncommon
Vascular Disorders	Flushing[a] Hypertension[a]	Uncommon Uncommon

a: Systemic effects

* At the application site, Tightness of jaw and pain in jaw with nicotine gum formulation

** Higher frequency observed in clinical studies with inhaler formulation

*** identified only for formulations administered during night

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.

$ Reported the same or less frequently than placebo

§ Frequency calculated from meta-analysis of clinical trial data. When term was identified from post- marketing safety data but was not reported in clinical trials frequency "unknown" is stated

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

Excessive use of nicotine from either NRT and/or smoking/ vaping might cause symptoms of an overdose.

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.

If mouth spray is ingested, activated charcoal should be given as soon as possible.

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

For risk assessment and advice on the management of overdose please contact the National Poisons Centre on 0800 POISON (0800 764766)

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Drug for treatment of nicotine dependence. ATC code: N07B A01.

NICORETTE® QUICKMIST is a treatment-aid in smoking cessation.

Abrupt cessation of the established, regular use of tobacco-containing products results in the characteristic syndrome, with withdrawal symptoms including cravings (urges to smoke).

Clinical studies have shown that nicotine replacement products can help smokers abstain from or reduce their smoking.

Clinical studies in vapers

A parallel, double-blind, placebo-controlled, randomised pharmacodynamic study conducted in solus, regular vapers has shown that the mouth spray is effective in relieving momentary urges to vape (cravings) following ad lib use of the spray over 11 hours. A significantly higher proportion of subjects ($p<0.001$) in the mouth spray group (82.6%) had a maximum reduction of at least 50% vs. baseline in momentary urges-to-vape scores during the two hours follow-up compared to the placebo group (55.1%).

Long-term data on vaping cessation is not available. No studies have been conducted in a paediatric (<18 years) population,

5.2 Pharmacokinetic properties

The pharmacokinetics of nicotine has been extensively studied, and variations in delivery format have been found to have significant effects on rate and extent of absorption.

The pharmacokinetics of the mouth spray has been studied in 4 studies. The studies enrolled a total of 141 subjects.

The oral spray form means that the nicotine dose is administered instantaneously, and as a result the absorption of nicotine from the mouth spray is rapid: In trials, nicotine uptake from the oral nicotine spray was detected at 2 minutes, the first timepoint tested.

A maximum concentration of 5.3ng/mL is reached within 13 minutes after administration of a 2mg dose. The nicotine AUCs over the first 10 minutes after administration of the mouth spray at a dose of 1 and 2mg exceeds those observed with nicotine gum and nicotine lozenge at doses of 4 mg (0.48 and 0.64h*ng/mL vs. 0.33 and 0.33h*ng/mL).

AUC∞ estimates show that the bioavailability of nicotine administered by mouth spray is similar to or somewhat higher than that of nicotine gum or lozenge.: The nicotine AUC∞ for the mouth spray 2mg was 14.0h*ng/mL as compared with 23.0h*ng/mL and 26.7h*ng/mL for nicotine gum 4mg and nicotine lozenge 4mg, respectively.

Steady-state average nicotine plasma concentrations achieved after administration of the maximum dose (i.e. 2 sprays of the mouth spray 1mg every 30 minutes) are in the order of magnitude approximately 28.8ng/mL as compared with 23.3ng/mL for nicotine gum 4mg (1 gum, hourly) and 25.5ng/mL for nicotine lozenge 4mg (1 lozenge, hourly).

There is a very small deviation from dose-linearity of AUC_{∞} and C_{max} after administration of the mouth spray as shown with single doses of 1, 2, 3 and 4 sprays.

The volume of distribution following IV administration of nicotine is about 2 to 3L/kg. The major eliminating organ is the liver, 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, is eliminated with a terminal half-life of 15 to 20 hours and the plasma concentrations of cotinine exceed that of nicotine by 10-fold.

The mean plasma clearance of nicotine is about 70L/hour and the elimination half-life is 2-3 hours.

The primary urinary metabolites are cotinine (12% of the molar absorbed nicotine dose) and trans- 3-hydroxy-cotinine (37% 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. Nicotine clearance was on average decreased by 50 % in smokers with severe renal impairment. Raised nicotine levels have been seen in smokers undergoing hemodialysis.

The pharmacokinetics of nicotine is unaffected in cirrhotic patients with mild liver impairment (Child-Pugh score 5). However, in smokers with moderately impaired liver function (Child-Pugh score 7), total clearance has been reported to be reduced by 40% - 50%. There are no data about nicotine pharmacokinetics in smokers with a Child-Pugh score exceeding 7.

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

5.3 Preclinical safety data

In vitro genotoxicity testing of nicotine has yielded predominantly negative results. There are some equivocal results when testing at high nicotine concentrations.

In vivo tests of genotoxicity have been negative.

Animal experiments have shown that nicotine exposure results in decreased birth-weight decreased litter size and decreased survival of offspring.

Results of carcinogenicity assays do not provide any clear evidence of a tumorigenic effect of nicotine.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

NICORETTE® QUICKMIST Mouth Spray 1mg nicotine/spray Freshmint Flavour
Propylene glycol
Anhydrous ethanol

Trometamol
Poloxamer 407
Glycerol
Sodium hydrogen carbonate
Levomenthol
Mint flavour
Cooling flavour
Sucralose
Acesulfame potassium
Hydrochloric acid
Purified water

NICORETTE® QUICKMIST Mouth Spray 1mg nicotine/spray Cool Berry Flavour
Propylene glycol
Anhydrous ethanol
Trometamol
Poloxamer 407
Glycerol
Sodium hydrogen carbonate
Levomenthol
Berry flavour
Cooling flavour
Sucralose
Acesulfame potassium
Hydrochloric acid
Purified water

6.2 Incompatibilities

None known

6.3 Shelf life

2 years.

6.4 Special precautions for storage

Store below 25°C.

6.5 Nature and contents of container

NICORETTE® QUICKMIST (Freshmint and Cool Berry Flavour): 1x1 dispenser, 2x1 dispensers.

13.2 ml is filled in a PET bottle. One bottle contains 150 sprays of 1 mg. The bottle is placed in a dispenser with a mechanical spray pump. The dispenser has a child resistant feature.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal

Dispose of carefully. Any unused medicine or waste material should be disposed of in accordance with local requirements

7. MEDICINE SCHEDULE

General Sale Medicine.

8. SPONSOR

JNTL Consumer Health (New Zealand) Ltd 507 Mt Wellington Highway

Mt Wellington, Auckland 1060 Telephone: 0800 446 147

9. DATE OF FIRST APPROVAL

Date of publication in the New Zealand Gazette of consent to distribute the medicine: 16 December 2011

10. DATE OF REVISION OF THE TEXT

11 October 2024