Professional information for NICORETTE® ICY WHITE 2 mg and 4 mg

SCHEDULING STATUS

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1. NAME OF THE MEDICINE

NICORETTE® ICY WHITE 2 mg gum

NICORETTE® ICY WHITE 4 mg gum

NICORETTE® FRESHFRUIT 2 mg gum

NICORETTE® FRESHFRUIT 4 mg gum

NICORETTE® FRESHMINT 2 mg gum

NICORETTE® FRESHMINT 4 mg gum

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

NICORETTE® ICY WHITE 2 mg: each piece contains 10 mg nicotine-resin complex 20 %, equivalent to 2 mg nicotine.

Sugar free.

Excipients with known effect:

Contains sweeteners: each piece contains 3,5 mg sucralose and 2 mg acesulfame potassium.

Contains sugar alcohol: each piece contains 591,5 mg xylitol.

NICORETTE® ICY WHITE 4 mg: each piece contains 20 mg nicotine-resin complex 20 %, equivalent to 4 mg nicotine.

Sugar free.

Excipients with known effect:

Contains sweeteners: each piece contains 3,5 mg sucralose and 2 mg acesulfame potassium.

Contains sugar alcohol: each piece contains 579,5 mg xylitol.

NICORETTE® FRESHFRUIT 2 mg: each piece contains 10 mg nicotine-resin complex 20 %, equivalent to 2 mg nicotine.

Sugar free.

Excipients with known effect:

Contains sweeteners: each piece contains 5 mg sucralose and 2 mg acesulfame potassium.

Contains sugar alcohol: each piece contains 591,5 mg xylitol.

NICORETTE® FRESHFRUIT 4 mg: each piece contains 20 mg nicotine-resin complex 20 %, equivalent to 4 mg nicotine.

Sugar free.

Excipients with known effect:

Contains sweeteners: each piece contains 5 mg sucralose and 2 mg acesulfame potassium.

Contains sugar alcohol: each piece contains 579,5 mg xylitol.

NICORETTE® FRESHMINT 2 mg: each piece contains 10 mg nicotine-resin complex 20 %, equivalent to 2 mg nicotine.

Sugar free.

Excipients with known effect:

Contains sweetener: each piece contains 2 mg acesulfame potassium.

Contains sugar alcohol: each piece contains 608 mg xylitol.

NICORETTE® FRESHMINT 4 mg: each piece contains 20 mg nicotine-resin complex 20 %, equivalent to 4 mg nicotine.

Sugar free.

Excipients with known effect:

Contains sweetener: each piece contains 2 mg acesulfame potassium.

Contains sugar alcohol: each piece contains 596 mg xylitol.

For the full list of excipients, see section 6 .1.

3. PHARMACEUTICAL FORM

Gum.

NICORETTE® ICY WHITE 2 mg: A whitish coated, square piece of gum.

NICORETTE® ICY WHITE 4 mg: A cream coloured coated, square piece of gum.

NICORETTE® FRESHFRUIT 2 mg: A square, whitish coated piece, with a characteristic fruity taste and odour.

NICORETTE® FRESHFRUIT 4 mg: A square, coated and cream coloured piece, with a characteristic fruity taste and odour.

NICORETTE® FRESHMINT 2 mg: A square, whitish coated piece, with a characteristic minty taste and odour.

NICORETTE® FRESHMINT 4 mg: A square, coated and cream coloured piece, with a characteristic minty taste and odour.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

NICORETTE® is indicated as a temporary aid to the cigarette smoker seeking to give up his or her smoking habit while participating in a behavioural modification programme under professional supervision. The efficacy of NICORETTE® use without concomitant participation in a behavioural modification programme has not been established. The benefits of NICORETTE® use beyond three months have not been demonstrated.

4.2 Posology and method of administration

Adults:

Use the gum for 3 months. Gradual weaning from the gum should then be initiated. Treatment should be stopped when the dose is reduced to 1 - 2 chewing gums per day.

1. The patient must give up smoking completely. The gradual cutting down of tobacco consumption will not work.
2. NICORETTE® has been prescribed as part of a programme to help the patient stop smoking.
3. Whenever the patient feels the need to smoke, one piece of gum should be placed in the mouth.
4. When the gum is chewed, nicotine is slowly released and is absorbed through the lining of the mouth.
5. The gum should be chewed very slowly until it is tasted or a slight tingling is felt in the mouth. Because of its nicotine content, the gum does not taste like an ordinary chewing gum.
6. As soon as the gum can be tasted, chewing must stop.
7. After the taste or tingling is almost gone (about one minute), the gum should be chewed slowly again until the taste is more pronounced. Then chewing should be stopped again.
8. The gum should be chewed slowly for 30 minutes to release most of the nicotine. The patient should not expect the gum to give the same quick satisfaction that smoking does.
9. Most people find that 10 to 12 pieces per day of NICORETTE® 2 mg or 4 mg are enough to control their urge to smoke. If this is not the case, consult your doctor or pharmacist. Do not use more than 15 pieces in 24 hours. Depending on the patient's needs, the rate of chewing and the time between pieces can be adjusted.

Special populations:

Children:

Not to be administered to children.

4.3 Contraindications

Hypersensitivity to nicotine or to any of the excipients (see section 6.1).

Safety and effectiveness in children and adolescents who smoke have not been evaluated.

NICORETTE® should not be given to children.

NICORETTE® is contraindicated in patients during the immediate post-myocardial infarction period, in patients with life-threatening dysrhythmias, and patients with severe or worsening angina pectoris. NICORETTE® is also contraindicated in patients with active temporomandibular joint disease.

4.4 Special warnings and precautions for use

The risks of nicotine use in patients with certain cardiovascular and endocrine diseases should be carefully weighed against the benefits of including NICORETTE® in a smoking cessation programme in these patients. Specifically, patients with coronary heart disease (history of myocardial infarction and/or unstable or worsening angina pectoris), serious cardiac dysrhythmias or vasospastic diseases (Buerger's disease, Prinzmetal variant angina), recent cerebrovascular accident should be carefully screened and evaluated before NICORETTE® is prescribed. Non-pharmacological interventions, such as counselling should be considered.

As the action of nicotine on the adrenal medulla (release of catecholamines) does not appear to be affected by tolerance, NICORETTE® should be used with caution in patients with hyperthyroidism, phaeochromocytoma or insulin-dependent diabetes.
Patients with diabetes mellitus should be advised to monitor their blood sugar levels more closely than usual when smoking is stopped, and NICORETTE® is initiated as reductions in nicotine-induced catecholamine release can affect carbohydrate metabolism.

NICORETTE® should be used with caution in patients with moderate to severe hepatic impairment and/or severe renal impairment as the clearance of nicotine or its metabolites may be decreased with a potential increase in adverse effects.

Cigarette smoking is felt to play a perpetuating role in hypertension and peptic ulcer disease. Therefore, NICORETTE® should be used in patients with systemic hypertension or inactive peptic

ulcer only when the benefits of including NICORETTE® in a smoking cessation programme outweigh the risks.

Nicotine may exacerbate symptoms in patients suffering from oesophagitis, gastric or peptic ulcers and NICORETTE® should be used with caution in these conditions.

In females, tobacco smoking delays time to conception, decreases *in vitro* fertilisation success rates, and increases risk of infertility. In males, tobacco smoking reduces sperm production, increases oxidative stress and DNA damage. Spermatozoa from smokers have reduced fertilising capacity. The specific contribution of nicotine however, to these effects in humans, is unknown (see section 4.6).

If the gum is chewed too fast, the patient may experience effects similar to those experienced when inhaling cigarette smoke for the first time, or when smoking too fast. These effects include light-headedness, nausea and vomiting, throat and mouth irritation, hiccups and stomach upset. Most of these effects are controlled by chewing more slowly. See instructions below.
Some other effects sometimes seen particularly during the first few days of using gum include mouth ulcers, jaw muscle ache, headache, heart palpitations and more than the usual amount of saliva in the mouth. There are other side effects which have been infrequently reported with the use of NICORETTE®. Patients should be encouraged to discuss any questions, and to report any disturbing side effects. Do not exceed the recommended dosage.

As the urge to smoke fades, gradually reduce the number of pieces of gum chewed each day. This may be possible within two or three months. Unless advised otherwise, no attempt to stop using the gum should be made until the craving is satisfied with one or two pieces a day. The gum should not be used for more than 3 months.

Patients should remember to carry the gum with them at all times in case they feel the sudden urge to smoke again. THEY SHOULD NOT FORGET THAT ONE CIGARETTE IS ENOUGH TO START THE SMOKING HABIT AGAIN.

Smokers who wear dentures may experience difficulty in chewing nicotine gum. The chewing gum may stick to, and in rare cases, damage dentures.

Children:

Not to be administered to children.

Doses of nicotine tolerated by smokers can produce severe toxicity in children that may be fatal. Products containing nicotine should not be left where they may be handled or ingested by children (see section 4.9).

Some flavours of NICORETTE® chewing gum contains xylitol, which may cause diarrhoea and flatulence when taken orally in large amounts.

Transferred dependence:

Transferred dependence can occur, but is unusual and is both less harmful and easier to break than smoking dependence.

Stopping smoking:

Polycyclic aromatic hydrocarbons in tobacco smoke induce the metabolism of medicines metabolised by CYP1A2. When a smoker stops smoking, this may result in slower metabolism and a consequent rise in blood levels of such medicines. This is of potential clinical importance for products with a narrow therapeutic window, e.g. theophylline, tacrine, clozapine and ropinirole (see section 4.5).

4.5 Interaction with other medicines and other forms of interaction

No clinically relevant interactions between NICORETTE® and other medicines have definitely been established. However, NICORETTE® may possibly enhance the haemodynamic effects of adenosine (increase in blood pressure and heart rate and also increased pain response (angina pectoris type chest pain) provoked by adenosine administration) (see section 4.4).

Smoking cessation, with or without nicotine substitutes, may alter response to concomitant medicines in ex-smokers. Smoking is considered to increase metabolism and thus lower blood levels of medicines such as caffeine, theophylline, imipramine and pentazocine, through enzyme induction.

Cessation of smoking may result in increased levels of these medicines. Absorption of glutethimide may be decreased and the “first pass” metabolism of propoxyphene decreased by smoking cessation. Other reported effects of smoking, which do not involve enzyme induction, include reduced diuretic effects of furosemide and decreased cardiac output, and increased blood pressure with propranolol, which may also relate to the hormonal effects of nicotine. Smoking cessation may reverse these actions (see section 4.4).

Both smoking and nicotine can increase circulating cortisol and catecholamines. Therapy with adrenergic agonists or with adrenergic blockers may need to be adjusted according to changes in nicotine therapy or smoking status.

4.6 Fertility, pregnancy and lactation

Women of childbearing potential / contraception in males and females:

In contrast to the well-known adverse effects of tobacco smoking on human conception and pregnancy, the effects of therapeutic nicotine treatment are unknown. Thus, whilst to date no specific advice regarding the need for female contraception has been found to be necessary, the most prudent state for women intending to become pregnant to be in is to be both non-smoking, and not using NICORETTE®.

Whilst smoking may have adverse effects on male fertility, no evidence exists that particular contraceptive measures are required during NICORETTE® treatment by males.

Pregnancy:

NICORETTE® may cause foetal harm when administered to a pregnant woman. NICORETTE® is therefore contraindicated in women who are or may become pregnant, and female patients should be advised to take adequate precautions to avoid becoming pregnant. The doctor may wish to consider a pregnancy test before instituting therapy with NICORETTE®. If NICORETTE® is used during pregnancy, or if the patient becomes pregnant while taking NICORETTE®, the patient should be apprised of the potential hazard to the foetus. Nicotine passes to the foetus and affects its breathing movements and circulation. The effect on circulation is dose dependant. Therefore, the pregnant smoker should always be advised to stop smoking completely without use of nicotine replacement therapy. The risk of continued smoking may pose a greater hazard to the foetus as compared with the use of nicotine replacement products in a supervised smoking cessation programme.

Maternal smoking in pregnancy is associated with low birth weight infants and increased risk of abortion, premature birth, still birth and neonatal death. Stopping smoking is the single most effective intervention for improving the health of both the pregnant smoker and her baby.
The earlier abstinence is achieved the better.

Lactation:

Because of the potential for serious adverse reactions to nursing infants from nicotine, a decision should be made whether to discontinue NICORETTE®.
Nicotine passes freely into breast milk in quantities that may affect the infant, even at therapeutic doses, and therefore should not be used by mothers breastfeeding their infants. As nicotine is the major addictive substance in tobacco smoke, the possibility exists that dependence on the nicotine in NICORETTE® may occur.

Should smoking cessation not be achieved, use of the gum by breastfeeding smokers should only be initiated after advice from a health care provider.

Women should take NICORETTE® as soon as possible after breastfeeding.

Fertility:

In females, tobacco smoking delays time to conception, decreases *in-vitro* fertilisation success rates, and significantly increases the risk of infertility. In males, tobacco smoking reduces sperm production, increases oxidative stress, and DNA damage. Spermatozoa from smokers have reduced fertilising capacity. The specific contribution of nicotine to these effects in humans is unknown.

4.7 Effects on ability to drive and use machines

NICORETTE® can cause dizziness. Patients should ensure that they know how NICORETTE® affects their ability to drive and use machines, before engaging in these activities.

4.8 Undesirable effects

Effects of smoking cessation:

Regardless of the means used, a variety of symptoms are known to be associated with quitting habitual tobacco use. These include emotional or cognitive effects such as dysphoria or depressed mood; insomnia; irritability, frustration or anger; anxiety; difficulty concentrating, and restlessness or impatience. There may also be physical effects, such as decreased heart rate, increased appetite or weight gain, dizziness or presyncopal symptoms, cough, constipation, gingival bleeding/aphthous ulceration, or nasopharyngitis. In addition, and of clinical significance, nicotine cravings may result in profound urges to smoke.

Adverse reactions:

Most of the undesirable effects reported by the subjects occur during the early phase of treatment and are mainly dose dependent.
Allergic reactions (including symptoms of anaphylaxis) occur rarely during use of nicotine products.

Mechanical effects of gum chewing include traumatic injury to oral mucosa or teeth. Nicotine from NICORETTE® may sometimes cause irritation of the throat and mouth (most subjects adapt to this with ongoing use) and may also cause increased salivation and sometimes swelling of the tongue. Excessive swallowing of dissolved nicotine (in the saliva) may cause hiccups.
Excessive consumption of NICORETTE® could lead to nausea, faintness or headaches, diarrhoea, constipation, vomiting, hoarseness, dry mouth, flushing, sneezing, cough, euphoria, insomnia, dizziness, eructation, indigestion, anorexia, jaw muscle ache and atrial fibrillation.

Swallowed nicotine may exacerbate symptoms in patients suffering from gastritis or peptic ulcer.
Smokers who wear dentures may experience difficulty in chewing NICORETTE®.
NICORETTE® should be used with caution in patients with oral or pharyngeal inflammation and in patients with a history of oesophagitis or peptic ulcer.

Immune system disorders:

Less frequent: Allergic reactions including angioedema, hypersensitivity[a]

Nervous system disorders:

Frequent: Headache, dizziness, dysgeusia, paraesthesia[a]

Cardiac disorders:

Less frequent: Palpitations, reversible atrial fibrillation

Respiratory, thoracic and mediastinal disorders:

Frequent: Cough, throat irritation

Gastrointestinal disorders:

Frequent: Gastrointestinal discomfort, hiccups, nausea, vomiting, diarrhoea, abdominal pain, dry mouth, dyspepsia, flatulence, stomatitis, salivary hypersecretion

Skin and subcutaneous tissue disorders:

Less frequent: Erythema, urticaria

General disorders and administration site conditions:

Frequent: Sore mouth or throat, jaw muscle ache, burning sensation*, fatigue[a]

[a] Systemic effects

* At the application site

Post-marketing experience

Immune system disorders:

Frequency unknown: Anaphylactic reaction**

Psychiatric disorders:

Less frequent: Abnormal dream**,***

Eye disorders:

Less frequent: Blurred vision, increased lacrimation

Cardiac disorders:

Less frequent: Tachycardia**

Vascular disorders:

Less frequent: Flushing**, hypertension**

Respiratory, thoracic and mediastinal disorders:

Less frequent: Bronchospasm, dysphonia, dyspnoea**, nasal congestion, oropharyngeal pain, sneezing, throat tightness

Gastrointestinal disorders:

Less frequent: Dry throat, dysphagia, eructation, glossitis, oral hypoaesthesia, oral mucosal blistering and exfoliation, lip pain, oral paraesthesia, retching

Skin and subcutaneous tissue disorders:

Less frequent: Hyperhidrosis**, pruritus**, rash**

Musculoskeletal, connective tissue and bone disorders:

Less frequent: Pain in jaw, muscle tightness

General disorders and administrative site conditions:

Less frequent: Asthenia**, chest discomfort and pain**, malaise**

** Systemic effects

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of NICORETTE® is important. It allows continued monitoring of the benefit/risk balance of NICORETTE®. Healthcare providers are asked to report any suspected adverse reactions to SAHPRA via the "**6.04 Adverse Drug Reaction Reporting Form**", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8.

4.9 Overdose

Symptoms of overdose with nicotine from NICORETTE® may occur in smokers who have previously had a low nicotine intake from cigarettes or if other sources of nicotine are used concomitantly with NICORETTE®.

Acute or chronic toxicity of nicotine in man is highly dependent on mode and route of administration. Adaptation to nicotine (e.g. in smokers) is known to significantly increase tolerability compared with non-smokers. The acute minimum lethal oral dose of nicotine is believed to be 40 to 60 mg in children (oral intake of tobacco from cigarettes) or 0,8 to 1,0 mg/kg in adult non-smokers.

Overdosage of NICORETTE® can only occur if many pieces are chewed simultaneously. The fatal dose of nicotine in man is about 60 mg.

Symptoms of overdosage are those of acute nicotine poisoning and include nausea, increased salivation, abdominal pain, vomiting, diarrhoea, cold sweat, headache, dizziness, disturbed hearing and vision, mental confusion and marked weakness. Faintness and prostration may ensue and hypotension may occur, breathing is difficult, the pulse may be rapid, weak and irregular. Collapse may be followed by terminal convulsions.

Death may result within a few minutes from respiratory failure caused by paralysis of the muscles of respiration. Nicotine is excreted four times more rapidly in acid than alkaline urine.

Doses of nicotine that are tolerated by adult smokers during treatment may produce severe symptoms of poisoning in children and may prove fatal. Suspected nicotine poisoning in a child should be considered a medical emergency and treated immediately.

The risk of poisoning as a result of swallowing the gum is very small, as absorption in the absence of chewing is slow and incomplete.

If the patient accidentally swallows a piece of gum, no adverse effects should be experienced. Overdose could occur if many pieces are chewed simultaneously or in rapid succession. IN CASE OF ACCIDENTAL OVERDOSAGE OR IF A CHILD CHEWS OR SWALLOWS ONE OR MORE PIECES OF THE GUM, A DOCTOR OR THE LOCAL POISON CONTROL CENTRE SHOULD BE CONTACTED IMMEDIATELY.

In the event of overdosage, vomiting should be induced with syrup of ipecacuanha or gastric lavage carried out (wide bore tube). A suspension of activated charcoal should then be passed through the tube and left in the stomach. Artificial respiration with oxygen should be instituted if needed and continued for as long as necessary. Other therapy, including treatment of shock, is purely symptomatic.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Category and class: A 34. Other

Pharmacotherapeutic group: Drug used in nicotine dependence

ATC code: N07B A01

Nicotine is an agonist at nicotine receptors in the peripheral and central nervous system (CNS) and has pronounced CNS and cardiovascular effects.

Abrupt cessation of the established, regular use of tobacco-containing products results in the characteristic syndrome, with withdrawal symptoms including cravings (urges to smoke) as described in section 4.8. Clinical studies have shown that nicotine replacement products can help smokers abstain from or reduce their smoking by relieving these withdrawal symptoms. The majority of smokers will gain weight on stopping smoking. In clinical trials, nicotine replacement therapy has been shown to attenuate post-cessation weight gain.

When used as directed, the 2 mg strengths produce peak blood nicotine concentrations equivalent to ⅓, and the 4 mg strengths produce peak blood nicotine concentrations equivalent to

⅔ that of smoking a mild cigarette. Owing to the slower rate of absorption of nicotine through the buccal mucosa, it does not reproduce the pleasure of cigarette smoking.
Although one is still supplying the body with nicotine, the blood levels achieved after repeated administration of NICORETTE® are less than those achieved after smoking.

5.2 Pharmacokinetic properties

Absorption:

Nicotine administered in chewing gums is readily absorbed from the oral mucosa membrane. Demonstrable blood levels of nicotine are obtained within 5 – 7 minutes after starting chewing and reaches a maximum about 5 – 10 minutes after stopping chewing. The amount of nicotine absorbed depends on the proportion of the dose extracted from the gum and the proportion lost due to swallowing and subsequent first-pass elimination in the liver.

Distribution:

The volume of distribution, following intravenous administration of nicotine, is about 2 to 3 L/kg and half-life is about 2 to 3 hours. Plasma protein binding of nicotine is less than 5 %. Therefore, changes in nicotine binding from use of concomitant medicines or alterations of plasma proteins by disease states would not be expected to have significant effects on nicotine pharmacokinetics.

Biotransformation:

Results of pharmacokinetic studies suggest that nicotine metabolism and elimination are independent of the choice of nicotine formulation, and thus results from studies with intravenous administration of nicotine are used to describe distribution, biotransformation, metabolism and excretion.

The major eliminating organ is the liver, although the lungs and brain also metabolise nicotine to a small extent. The enzyme primarily involved in biotransformation of nicotine is CYP2A6.

Seventeen 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 a terminal half-life of 15 to 20 hours and plasma 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).

Elimination:

The major eliminating organ is the liver, and average plasma clearance is about 70 L/hour. The kidneys and lungs also metabolise nicotine.

The primary urinary metabolites of nicotine are cotinine and trans-3-hydroxycotinine. On average 10 – 12 % of the absorbed nicotine dose is excreted as cotinine and 28 – 37 % of the dose is excreted as trans-3-hydroxycotinine.

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.

Mean AUC_{∞} of 14,7 and 28,2 ng/mL x h have been achieved following administration of 2 mg and 4 mg gum respectively.

Renal impairment:

Progressive severity of renal impairment is associated with decreased total clearance of nicotine. Nicotine clearance was decreased by 50 % on average in subjects with severe renal impairment. Raised nicotine levels have been seen in smoking subjects undergoing haemodialysis.

Hepatic impairment:

The pharmacokinetics of nicotine is unaffected in cirrhotic patients with mild liver impairment (Child Pugh score 5) and decreased on average by 40 – 50 % in cirrhotic patients with moderate liver impairment (Child Pugh score 7). There is no data about pharmacokinetics of nicotine in smokers with a Child-Pugh score exceeding 7.

Geriatric:

Total clearance of nicotine is reduced in healthy elderly subjects, but deviations are variable and not considered sufficiently important to justify general age-dependent dose adjustments.

5.3 Preclinical safety data

Summary:

In vitro and *in vivo* genotoxicity testing of nicotine has yielded predominantly non-genotoxic results. Some positive findings from *in vitro* and *in vivo* genotoxicity tests have been reported but investigations using regulatory accepted assays and protocols have shown no evidence of genotoxic activity at therapeutic doses.

Analysis of the results from long-term carcinogenicity assays data with nicotine or cotinine, major nicotine metabolite, predominately indicate nicotine does not have any significant or relevant carcinogenic activity.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

NICORETTE® ICY WHITE 2 mg:

Acesulfame potassium

Carnauba wax

Chewing gum base

Hypromellose

Levomenthol

Magnesium oxide light

Peppermint oil

Polysorbate 80

Sodium carbonate anhydrous

Sodium hydrogen carbonate

Starch

Sucralose

Titanium dioxide (E171)

Winterfresh

Xylitol.

NICORETTE® ICY WHITE 4 mg:

Acesulfame potassium

Carnauba wax

Chewing gum base

Hypromellose

Levomenthol

Magnesium oxide light

Peppermint oil

Polysorbate 80

Quinoline yellow (E104)

Sodium carbonate anhydrous

Starch

Sucralose

Titanium dioxide (E171)

Winterfresh

Xylitol.

NICORETTE® FRESHFRUIT 2 mg:

Acacia

Acesulfame potassium

Carnauba wax

Chewing gum base

Hypromellose

Levomenthol

Magnesium oxide light

Peppermint oil

Polysorbate 80

Sodium carbonate anhydrous

Sodium hydrogen carbonate

Sucralose

Titanium dioxide (E171)

Tuttifrutti (QL84441)

Xylitol.

NICORETTE® FRESHFRUIT 4 mg:

Acacia

Acesulfame potassium

Carnauba wax

Chewing gum base

Hypromellose

Levomenthol

Magnesium oxide light

Peppermint oil

Polysorbate 80

Quinoline yellow (E104)

Sodium carbonate anhydrous

Sodium hydrogen carbonate

Sucralose

Titanium dioxide (E171)

Tuttifrutti (QL84441)

Xylitol.

NICORETTE® FRESHMINT 2 mg:

Acacia

Acesulfame potassium

Carnauba wax

Chewing gum base

Levomenthol

Magnesium oxide light

Peppermint oil

Sodium carbonate anhydrous

Sodium hydrogen carbonate

Titanium dioxide (E171)

Xylitol.

NICORETTE® FRESHMINT 4 mg:

Acacia

Acesulfame potassium

Carnauba wax

Chewing gum base

Levomenthol

Magnesium oxide light

Peppermint oil

Quinoline yellow (E104)

Sodium carbonate anhydrous

Titanium dioxide (E171)

Xylitol.

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years.

Store at or below 25 °C.

6.4 Special precautions for storage

Protect from light. Keep in a cool place.

Keep any spare blisters in the box until immediately before use.

KEEP OUT OF REACH OF CHILDREN.

6.5 Nature and contents of container

NICORETTE® ICY WHITE 2 mg & 4 mg, NICORETTE® FRESHFRUIT 2 mg & 4 mg,

NICORETTE® FRESHMINT 2 mg & 4 mg:

Cartons of 30 and 105 pieces, in the form of 2 and 7 press-through aluminium/PVC/PVDC blister packed strips, each containing 15 pieces.

6.6 Special precautions for disposal and other handling

None.

7. HOLDER OF CERTIFICATE OF REGISTRATION

Johnson & Johnson (Pty) Ltd.

241 Main Road

Retreat 7945

SOUTH AFRICA

8. REGISTRATION NUMBERS

NICORETTE® ICY WHITE 2 mg: A46/34/0164

NICORETTE® ICY WHITE 4 mg: A46/34/0165

NICORETTE® FRESHFRUIT 2 mg: A40/34/0565

NICORETTE® FRESHFRUIT4 mg: A40/34/0566

NICORETTE® FRESHMINT 2 mg: A40/34/0520

NICORETTE® FRESHMINT 4 mg: A40/34/0523

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of registration:

NICORETTE® ICY WHITE 2 mg: 15 May 2019

NICORETTE® ICY WHITE 4 mg: 15 May 2019

NICORETTE® FRESHFRUIT 2 mg: 05 December 2013

NICORETTE® FRESHFRUIT4 mg: 05 December 2013

NICORETTE® FRESHMINT 2 mg: 05 December 2013

NICORETTE® FRESHMINT 4 mg: 05 December 2013

10. DATE OF REVISION OF THE TEXT

Will be allocated by SAHPRA upon approval.

Namibia:
Nicorette Freshmint 2 mg: 15/34/0032 NS0
Nicorette Freshmint 4 mg: 15/34/0033 NS0