NICORETTE® ICY WHITE 2 mg and 4 mg

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

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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

Nicotine

Sugar free.

Contains sweeteners:

NICORETTE® ICY WHITE 2 mg & 4 mg (each piece contains 3,5 mg sucralose and 2 mg acesulfame potassium)

NICORETTE® FRESHFRUIT 2 mg & 4 mg (each piece contains 5 mg sucralose and 2 mg acesulfame potassium)

NICORETTE® FRESHMINT 2 mg & 4 mg (each piece contains 2 mg acesulfame potassium)

Contains sugar alcohol:

NICORETTE® ICY WHITE 2 mg & NICORETTE® FRESHFRUIT 2 mg (each piece contains 591,5 mg xylitol)

NICORETTE® FRESHMINT 2 mg (each piece contains 608 mg xylitol)

NICORETTE® ICY WHITE 4 mg & NICORETTE® FRESHFRUIT 4 mg (each piece contains 579,5 mg xylitol)

NICORETTE® FRESHMINT 4 mg (each piece contains 596 mg xylitol)

Read all of this leaflet carefully because it contains important information for you.

NICORETTE® chewing gum is available without a doctor's prescription, for you to help you stop smoking. Nevertheless, you still need to use NICORETTE® chewing gum carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share NICORETTE® chewing gum with any other person.
- Ask your health care provider or pharmacist if you need more information or advice.

What is in this leaflet

1. What NICORETTE® chewing gum is and what it is used for.
2. What you need to know before you use NICORETTE® chewing gum.
3. How to use NICORETTE® chewing gum.
4. Possible side effects.
5. How to store NICORETTE® chewing gum.
6. Contents of the pack and other information.

1. What NICORETTE® chewing gum is and what it is used for

NICORETTE® chewing gum helps you to give up smoking by relieving nicotine craving, as well as the unpleasant withdrawal effects that smokers experience when they stop smoking.

NICORETTE® chewing gum is most effective if you use it while you participate in a behaviour modification programme to help you stop smoking. If you use NICORETTE® for longer than three months you may not experience any additional benefits.

2. What you need to know before you use NICORETTE® chewing gum

Do not use NICORETTE® chewing gum if:

- You are hypersensitive (allergic) to nicotine or any of the other ingredients of NICORETTE® chewing gums.

- You are under the age of 18 years.
- You are not a smoker.
- You have just suffered a heart attack.
- You have a severe heart condition that effects your heart rate or rhythm.
- You have severe chest pain (angina pectoris)
- You have a disease of the jaw joint.
- You are pregnant or breastfeeding your baby (see **Pregnancy, breastfeeding and fertility**).

Warnings and precautions

Take special care with NICORETTE® chewing gum

Ask your doctor or pharmacist for advice before using NICORETTE® chewing gum if:

- You have recently had a serious cardiovascular event like a stroke or heart attack.
- You have persistent indigestion or pains in the chest.
- You have uncontrolled high blood pressure.
- You have a stomach ulcer, an ulcer in your small intestines, inflammation of your stomach or inflammation of your oesophagus (the passage between your mouth and your stomach).
- You have an overactive thyroid gland.
- You have diabetes that is controlled with insulin (you may require lower doses of insulin as a result of smoking cessation).
- You have a tumour of the adrenal glands (phaeochromocytoma) – your doctor will have told you.
- You have severe/moderate liver or severe kidney disease.

The chewing gum may stick to, and may in rare cases damage dentures.

If you are a woman, smoking can cause a delay in you falling pregnant and significantly increase your risk of not falling pregnant.

If you are a man, smoking can reduce your sperm production and lower the fertilising capacity of your sperm.

If you chew NICORETTE® gum too fast, you may experience effects similar to smoking for the first time, such as light-headedness, nausea, vomiting, throat and mouth irritation, hiccups or stomach upset. These effects can be controlled if you chew more slowly.

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

Other medicines and NICORETTE® chewing gum

Always tell your health care provider if you are taking any other medicine. (This includes complementary or traditional medicines.)

This is especially important if you take medicines containing:

- Caffeine (stimulant found in coffee and some medicines)
- Theophylline (for asthma)
- Imipramine (for depression or mood disorders)
- Pentazocine (for severe pain)
- Glutethimide (for insomnia)
- Propoxyphene (for mild to moderate pain)
- Furosemide (for water retention associated with heart failure)
- Propanolol (for high blood pressure)

NICORETTE® chewing gum with food, drink and alcohol

See section 3.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding your baby, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before using NICORETTE® chewing gum, as it may cause harm to your baby.

Take adequate precautions to avoid becoming pregnant while using NICORETTE® chewing gum.

Your doctor may wish to consider a pregnancy test before starting therapy with NICORETTE® chewing gum. If you use NICORETTE® chewing gum during pregnancy or if you become pregnant while using NICORETTE® chewing gum, you should consider the potential hazard to your unborn baby.

NICORETTE® chewing gum should be avoided during breastfeeding as nicotine is excreted in breast milk and may affect your child.

If you are breastfeeding, you should only use NICORETTE® chewing gum after you have consulted with your health care provider. If you are going to use NICORETTE® chewing gum, you should use it as soon as possible after breastfeeding.

Driving and using machines

NICORETTE® can cause dizziness. Do not drive a vehicle, operate machinery, or do anything else that requires your attention until you know how NICORETTE® affects you.

NICORETTE® chewing gum contains xylitol

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

3. How to use NICORETTE® chewing gum

Do not share medicines prescribed for you with any other person.

The usual dose is one piece of NICORETTE® chewing gum whenever you feel the need to smoke.

Do not eat or drink while chewing NICORETTE® chewing gum.

Only chew one piece of NICORETTE® chewing gum at a time. The number of NICORETTE® chewing gum pieces you use per day will depend on your craving, it could be between 10 - 12 pieces per day.

You must not use more than 15 pieces of NICORETTE® chewing gum in 24 hours.

You can use NICORETTE® chewing gum for 3 months at the above-mentioned dose. Thereafter

you have to start using less NICORETTE® chewing gum pieces each day until you are not using any NICORETTE® chewing gum per day.

Regular use beyond 3 months is generally not recommended. Some ex-smokers may need longer treatment to avoid returning to smoking. Keep any unused chewing gum handy in case the urge to smoke suddenly returns.

Always use NICORETTE® chewing gum exactly as described in this leaflet or as your doctor or pharmacist have told you. Check with your doctor or pharmacist if you are not sure.

If you have the impression that the effect of NICORETTE® chewing gum is too strong or to weak, tell your doctor or pharmacist.

Which strength of chewing gum to use

Use NICORETTE® 2 mg chewing gum (any flavour) if you smoke 20 cigarettes or less daily.

Use NICORETTE® 4 mg chewing gum (any flavour) if you smoke more than 20 cigarettes daily or if you have previously failed a quitting attempt using the 2 mg gum.

How to chew NICORETTE® chewing gum

1. Stop smoking completely at the same time in order to increase your chances of success.
2. Chew a piece of chewing gum when you feel the need to smoke; the chewing gum is chewed to release nicotine.
3. Then stop chewing (rest) so that nicotine can be taken in through the lining of the mouth.
4. Nicotine swallowed in the saliva is not beneficial and in excess may irritate your throat or upset your stomach causing e.g. hiccups. To avoid this chew slowly until the taste becomes strong then stop and rest the chewing gum between gum and cheek.
5. When the taste fades, chew a few times until the taste gets strong, then rest the chewing gum again.
6. Keep chewing the gum for about half an hour.

7. When the chewing gum has lost its strength dispose of it carefully, such as back in the hole of the blister.
8. Do not swallow the gum.

If you use more NICORETTE® chewing gum than you should

Symptoms of overdosage are those of acute nicotine poisoning and include nausea, increased salivation, stomach pain, diarrhoea, sweating, headache, dizziness, disturbed hearing and marked weakness. In the event of overdosage, or if your child accidentally swallows NICORETTE® chewing gum, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre. Take this leaflet and the rest of the remaining NICORETTE® chewing gum with you so the doctor will know what you have taken.
Nicotine in high doses can be very dangerous and sometimes fatal if taken by children.

4. Possible side effects

NICORETTE® chewing gum like all other medicines may cause unwanted side effects in some people.
NICORETTE® chewing gum can have side effects.
Not all side effects reported for NICORETTE® chewing gum are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking NICORETTE® chewing gum, please consult your doctor, pharmacist or other health care provider for advice.

NICORETTE® chewing gum may cause side effects similar to those associated with nicotine from smoking or other tobacco use.
These are mainly dose-dependent. Most of the possible side effects occur during the first weeks after start of treatment.
If any of the following happens, stop taking NICORETTE® chewing gum and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing
- Rash or itching
- Fainting.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to NICORETTE® chewing gum. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- Chest pains
- Changes in the way your heart beats, for example if you notice it beating faster
- Sudden constriction of the small airways of your lung that can cause wheezing and shortness of breath (bronchospasm).

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

- Nausea (feeling sick)
- Stomach pains or discomfort
- Headache
- Dizziness
- Diarrhoea.

The most frequent side effects are:

- Taste disturbance or loss of taste
- Tingling or numbness of your hands and feet (pins and needles)
- Cough, throat irritation
- Sore mouth and throat, jaw muscle ache

- Dizziness, headache
- Discomfort from stomach or bowels, nausea, hiccups, vomiting
- Stomach pain, dry mouth, indigestion, flatulence (wind)
- Increased saliva
- Burning sensation in your mouth
- Feeling tired.

Less frequent side effects are:

- Sense of irregular hard or rapid heartbeat
- Redness of the skin
- Skin rash notable for pale red, raised, itchy bumps
- Reversible irregular rapid heartbeat
- Allergic reactions such as swelling of the skin
- Abnormal dreams
- Blurred vision, watery eyes
- High blood pressure
- Loss or damage to your voice
- Blocked nose, sneezing, tightness of your throat
- Dry throat, difficulty swallowing, burping (belching)
- Swollen, red, painful tongue
- Decreased feeling or sensitivity in the mouth, numbness or tingling of the mouth, mouth blisters
- Lip pain
- Excessive sweating
- Muscle tightness
- Unusual weakness
- Chest discomfort and pain
- General feeling of discomfort or being unwell or out of sorts (malaise).

Some symptoms may be related to withdrawal symptoms associated with abstinence from smoking, e.g. dizziness, headache, sleeplessness. Increased frequency of mouth ulcers may occur after abstinence from smoking. The relation to nicotine is unclear. The chewing gum may stick to, and may in rare cases, damage dentures.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist. You can also report side effects to SAHPRA via the "**6.04 Adverse Drug Reactions Reporting Form**", found online under SAHPRA's publications: http://www.sahpra.org.za/Publications/Index/8.

By reporting side effects, you can help provide more information on the safety of NICORETTE® chewing gum.

For further information, please contact the Johnson and Johnson call centre on 0860 410032 (landline).

5. How to store NICORETTE® chewing gum

As with all medicines keep NICORETTE® chewing gum out of reach of children.

Keep your medicine in a cool dry place where the temperature stays at or below 25 °C.

Protect from light.

Do not use NICORETTE® chewing gum if the blister is damaged or if the product has passed the expiry date printed on the carton.

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

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

When NICORETTE® chewing gum is no longer needed, dispose of it carefully where children or animals cannot get it.

6. Contents of the pack and other information

What NICORETTE® chewing gum contains

NICORETTE® ICY WHITE 2 mg chewing gum

- The active substance is nicotine resinate 10 mg equivalent to nicotine 2 mg.
- The other ingredients are chewing gum base, xylitol, peppermint oil, sodium carbonate anhydrous, sodium hydrogen carbonate, acesulfame potassium, levomenthol, magnesium oxide light, Winterfresh, hypromellose, sucralose, polysorbate 80, starch, titanium dioxide (E171), carnauba wax.

NICORETTE® ICY WHITE 4 mg chewing gum

- The active substance is nicotine resinate 20 mg equivalent to nicotine 4 mg.
- The other ingredients are chewing gum base, xylitol, peppermint oil, sodium carbonate anhydrous, acesulfame potassium, levomenthol, magnesium oxide light, quinoline yellow (E104), Winterfresh, hypromellose, sucralose, polysorbate 80, starch, titanium dioxide (E171), carnauba wax.

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

The other ingredients are chewing gum base, xylitol, sodium carbonate anhydrous, sodium hydrogen carbonate, magnesium oxide light, acesulfame potassium, peppermint oil, levomenthol, acacia, tuttifrutti (QL84441), hypromellose, sucralose, polysorbate 80, titanium dioxide (E171), and carnauba wax.

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

The other ingredients are chewing gum base, xylitol, sodium carbonate anhydrous, acesulfame potassium, magnesium oxide light, peppermint oil, levomenthol, acacia, titanium dioxide (E171),

quinoline yellow (E104), tuttifrutti (QL84441), hypromellose, sucralose, polysorbate 80 and carnauba wax.

NICORETTE® FRESHMINT 2 mg: each piece contains 10 mg nicotine-resin complex 20 %, equivalent to 2 mg nicotine.
The other ingredients are chewing gum base, xylitol, sodium carbonate anhydrous, sodium hydrogen carbonate, magnesium oxide light, acesulfame potassium, peppermint oil, levomenthol, acacia, titanium dioxide (E171), carnauba wax.

NICORETTE® FRESHMINT 4 mg: each piece contains 20 mg nicotine-resin complex 20 %, equivalent to 4 mg nicotine.
The other ingredients are chewing gum base, xylitol, sodium carbonate anhydrous, magnesium oxide light, acesulfame potassium, peppermint oil, levomenthol, acacia, titanium dioxide (E171), quinoline yellow (E104), carnauba wax.

What NICORETTE® chewing gum looks like and contents of the pack

NICORETTE® ICY WHITE 2 mg is a whitish coated square piece of gum.
NICORETTE® ICY WHITE 4 mg is a cream coloured coated square piece of gum.
NICORETTE® FRESHFRUIT 2 mg is a square whitish coated piece, with a characteristic fruity taste and odour.
NICORETTE® FRESHFRUIT 4 mg is a square, coated and cream coloured piece, with a characteristic fruity taste and odour.
NICORETTE® FRESHMINT 2 mg is a square whitish coated piece, with a minty taste and odour.
NICORETTE® FRESHMINT 4 mg is a square, coated and cream coloured piece, with a minty taste and odour.

NICORETTE® chewing gum is packed in 2 and 7 blister strips containing 15 pieces. They are supplied in a carton containing 30 and 105 pieces together with a professional information.

Holder of certificate of registration

Johnson & Johnson,

241 Main

Road, Retreat,

7945,

South Africa.

For further information please contact the Johnson & Johnson Call Centre at telephone

0860 410032

This leaflet was last revised in

Will be allocated by SAHPRA upon approval.

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® FRESHFRUIT 4 mg: A40/34/0566

NICORETTE® FRESHMINT 2 mg: A40/34/0520

NICORETTE® FRESHMINT 4 mg: A40/34/0523

Namibia:

Nicorette Freshmint 2 mg: 15/34/0032 NS0

Nicorette Freshmint 4 mg: 15/34/0033 NS0