

Package leaflet: Information for the user

nicorette®

4 mg medicated chewing gum

freshmint 4 mg medicated chewing gum

freshfruit 4 mg medicated chewing gum

nicotine

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

Always take this medicine exactly as described in this leaflet or as

your doctor or pharmacist have told you.

- Keep this leaflet. You may need to read it again.

- Ask your pharmacist if you need more information or advice.

- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

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

1. What Nicorette Gum is and what it is used for

Nicorette Gum is a nicotine replacement therapy (NRT).

It is used to relieve withdrawal symptoms and reduce the cravings for nicotine that you get when you try to stop smoking, or when you are cutting down the number of cigarettes you smoke while trying to stop smoking.

Nicorette Gum can also be used to relieve cravings and withdrawal symptoms when you cannot smoke, e.g. in smoke free areas such as on a plane or at the cinema.

2. What you need to know before you use Nicorette Gum

❗ Do not use Nicorette Gum:

- if you are allergic to nicotine or any of the other ingredients of this medicine (listed in section 6).
- if you are pregnant or breast feeding, unless advised by your doctor.
- If you are a non-smoker or are under 18 years of age.

⚠ Warnings and Precautions

Talk to your doctor, nurse or pharmacist before using Nicorette Gum...

- if you are in hospital because of heart disease (including heart attack, disorders of heart rate or rhythm, or stroke).
- if you have high blood pressure, bad circulation.
- if you have persistent indigestion or pains in the chest.
- if you have a stomach ulcer, duodenal ulcer, inflammation of the stomach or inflammation of the oesophagus (passage between the mouth and stomach).
- if you have liver or kidney disease.
- if you have an overactive thyroid gland or have a *phaeochromocytoma* (a tumour of the adrenal gland that can affect blood pressure) – your doctor will have told you this.
- if you have diabetes – monitor your blood sugar levels more often when starting to use Nicorette Gum as you may find your insulin or medication requirements alter.
- If you have a history of epilepsy or seizure.
- ▶ If any of these applies, talk to your doctor, nurse or pharmacist.
- ▶ **Transferred dependence:** Nicotine in any dose form can result in a dependence syndrome after continued use. Transferred dependence can occur with this medicine, but is unusual and is both less harmful and easier to break than smoking dependence.

❗ Other medicines and Nicorette Gum

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines including the following medicines as stopping smoking may require the doses of these medicines to be adjusted:

- theophylline to treat asthma
- tacrine for Alzheimer's disease
- clozapine or olanzapine for schizophrenia
- imipramine, clomipramine, fluvoxamine to treat depression

- ropinirole for Parkinson's disease
- pentazocine to treat pain
- flecainide or adenosine to treat irregular or fast heart beats

⚠ Nicorette 4 mg Gum contains sorbitol (E420), Butylated hydroxytoluene (E321) and ethanol

- Each 4 mg gum contains sorbitol. Sorbitol is a source of fructose. If your doctor has told you that you have an intolerance to some sugars or if you have been diagnosed with hereditary fructose intolerance (HFI), a rare genetic disorder in which a person cannot break down fructose, talk to your doctor before you take this medicine.
- Nicorette Freshmint Gum, Nicorette Freshfruit Gum and Nicorette Icy White Gum do not contain sorbitol.
- Nicorette Gums do not contain sugar (sucrose) or animal products.
- The chewing gum base contains butylated hydroxytoluene. This may cause local skin reactions (e.g. contact dermatitis) or irritation to the eyes and mucous membranes.
- This medicine contains less than 1 mmol sodium (23 mg) in each of these chewing gums, that is to say essentially 'sodium-free'.
- Nicorette 4 mg Gum contains 0.616 mg of alcohol (ethanol) in each gum. Nicorette Freshfruit 4 mg Gum contains 0.009 mg of alcohol (ethanol) in each gum. The amount in each gum is equivalent to less than 1 ml beer or 1 ml wine. The small amount of alcohol in this medicine will not have any noticeable effects.
- This medicine contains flavour with Cinnamal, Cinnamyl alcohol, Citral, Citronellol, Eugenol, Geraniol, Isoeugenol, Limonene, Linalool. These substances may cause allergic reactions.

⚠ Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you might be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

If you are pregnant: ideally, you should try to give up smoking without NRT. Do not use Nicorette Gum unless advised by your doctor.

If you are breast-feeding: Nicorette Gum should not be used during breast feeding.

3. How to use Nicorette Gum

- ❗ Always use this medicine exactly as described in this leaflet or as your doctor, nurse or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

❗ When to use Nicorette Gum

The following sections contain the dosage information for Nicorette Gum. This shows the number of gums you should be using, when you should take them, how you should take them and the maximum amount of time you should be using Nicotine Replacement Therapy (NRT) for.

Please read this information carefully and then go to the "How to stop smoking: your choice" section, which will help you decide which method to use to give up smoking.

- Use the "How to chew Nicorette Gum – the Nicorette Chewing Technique" instructions which follow. The method of chewing is NOT the same as that for ordinary chewing gum. This way of chewing ensures that the nicotine is correctly released from the gum.
- The number of Nicorette Gums you use each day will depend on how many cigarettes you smoked and how strong they are. See the dosing table to find out the dose you should take.
- The 2 mg gums should be used by people who smoke 20 or fewer cigarettes each day or by heavier smokers when they are cutting down the number and strength of the Nicorette gums they are using.
- The 4 mg gums should be used by people who smoke more than 20 cigarettes per day.

❗ Children under 18 years

Do not give this product to children under 18 years of age.

❗ Adults

Number of cigarettes you smoke per day	Dose of Gums
20 cigarettes or fewer	One 2 mg Gum as required to relieve cravings. One 4 mg Gum as

More than 20 cigarettes

required to relieve cravings.

cigarettes

- Use only one piece of gum at a time.
- Most people use between 8 to 12 gums per day.
- Do not use more than 15 gums per day.

❗ How to chew Nicorette Gum – The Nicorette Chewing Technique

The method of chewing Nicorette Gum is not the same as for ordinary chewing gum. Nicorette Gum is chewed to release nicotine then rested so that nicotine can be taken in through the lining of the mouth. If Nicorette Gum is chewed continuously, the nicotine is released too quickly and is swallowed. This may irritate your throat, upset your stomach or give you hiccups.

If you have false teeth you may have difficulty chewing the gum as Nicorette Gum could stick to them and on rare occasions, damage dentures. If you experience a problem, other types of nicotine replacement therapy such as a skin patch, inhaler or lozenge may be more suitable for you.

❗ The Nicorette Chewing Technique

1. Chew slowly until taste becomes strong.
 2. Rest between gum and cheek.
 3. Chew again when the taste has faded.
- Keep chewing like this for about half an hour. After this time the gum will have lost its strength and you should dispose of it carefully.

❗ How to stop smoking: your choice

Because smoking is an addiction, you may find it difficult to give up. From time to time you may still have strong urges to smoke but if you follow these recommendations, you have a good chance of quitting.

Some people may find it easier to set a quit date and stop **smoking immediately**.

Others who are unable or not ready to stop smoking abruptly, may benefit from **gradually reducing the number of cigarettes** they smoke each day until they feel able to stop completely.

If you find it hard to stop smoking using Nicorette Gums, you are worried that you will start smoking again without them or you find it difficult to reduce the number of Nicorette Gums you are using, talk to your doctor, nurse or pharmacist. Remember Nicorette Gums are not intended as a substitute for smoking, they are an aid to give up.

Use one of the three options which follows:

❗ Stopping Immediately

The idea is to stop smoking immediately and use the gum to relieve the cravings to smoke. After achieving this you then stop using the gums.

❗ Adults aged 18 years and over

See the following instruction which shows the basic step by step process. The times given below are the longest amount of time they should take, and you should try to achieve your move to the next step in the shortest time possible.

Make sure that you read the instructions for each step in the information which follows.

Step 1: Set a date to quit and stop smoking cigarettes completely.

Step 2: Use the gum for up to 12 weeks (3 months) to relieve your cravings to smoke. See the dosing table in "When to use Nicorette Gum" to decide which strength of gum to use and how often you can take it. Steadily reduce the number of gums you use per day until you have given up Nicorette gum completely.

▶ **For those using the 4 mg Nicorette Gum, the use of 2 mg Gum may be helpful when withdrawing from treatment.**

▶ **You might feel a sudden craving to smoke long after you have given up smoking and stopped using Nicorette Gum. Remember you can use nicotine replacement therapy again if this should happen.**

❗ Stopping Gradually

The idea is to start by gradually replacing some of your cigarettes with the gum. After achieving this you then give up cigarettes completely while using the gum. Finally, you give up using the gum.

❗ Adults aged 18 years and over

See the following instruction which shows the basic step by step process. The times given for steps 2 and 3 are the longest they should take, and you should try to

achieve your move to the next step in the shortest time possible.

Make sure that you read the instructions for each step in the information which follows.

Step 1: Work out how many cigarettes you smoke per day. Set a date to start reducing the number of cigarettes you smoke.

Step 2: Start reducing. Over the next few months, reduce the number of cigarettes you smoke by using Nicorette Gum when you feel the urge to smoke, until you feel ready to stop completely. See the dosing table in “When to use Nicorette Gum” to decide which strength of gum to use and how often you can take it.

► **For those using the 4 mg Nicorette Gum, the use of 2 mg gums may be helpful when withdrawing from treatment.**

► **If after 6 weeks you have not reduced the number of cigarettes you smoke, ask your doctor, nurse or pharmacist for advice.**

► **If an attempt to stop smoking completely has not been made after 6 months, ask your doctor nurse or pharmacist for advice.**

Step 3: Stop smoking. Cut out all cigarettes and continue using the gum for up to 3 months to relieve your cravings to smoke.

Step 4: Start reducing the use of the gum.

You should try to use fewer pieces of gum each day. When you are using only one or two pieces per day, you should stop completely.

❗ **During times you cannot smoke**

If you are a smoker and are in a situation where you are prohibited from smoking or it is inconvenient to smoke (e.g. in a smoke-free area such as on a plane or at the cinema), you can use Nicorette Gum to relieve any cravings you may experience.

❗ **Adults aged 18 years and over**

If you smoke less than 20 cigarettes per day, you should use the 2 mg gum; if you smoke 20 or more cigarettes you should use the 4 mg gum. Chew the gum using the correct chewing technique described in Section 3. Do not use more than 15 pieces of gum per day.

❗ **If you use more Nicorette Gum than you should**

If you have used more than the recommended dosage you may experience nausea (feeling sick), increased salivation, pain in your abdomen, diarrhoea, sweating, headache, dizziness, hearing disturbance or weakness.

► **If you do get any of these effects contact a doctor or your nearest hospital Accident and Emergency department immediately.** Take this leaflet and the pack with you.

❗ **If a child has used or swallowed the gums**

► **Contact a doctor or your nearest hospital Accident and Emergency department immediately. Nicotine ingestion by a child may result in severe poisoning.**

4. Possible side-effects

Like all medicines, this medicine can cause side-effects, although not everyone gets them. As many of the effects are due to nicotine, they can also occur when nicotine is obtained by smoking.

Effects related to stopping smoking (nicotine withdrawal)

You may experience unwanted effects because by stopping smoking you have reduced the amount of nicotine you are taking. You may also experience these effects if you under use Nicorette Gum before you are ready to reduce your nicotine intake.

These effects include: irritability or aggression, feeling low, anxiety, restlessness, poor concentration, increased appetite or weight gain, urges to smoke (craving), night time awakening or sleep disturbance and lowering of heart rate, dizziness, light headedness, blurry vision, nausea, coughs and colds, constipation, mouth ulcers or bleeding in the mouth, swelling of the nasal passages and back of the throat.

Effects of too much nicotine

You may also get these effects if you are not used to inhaling tobacco smoke.

These effects include: feeling faint, feeling sick (nausea), headache and hiccups (due to excessive swallowing of nicotine).

Side-effects of Nicorette Gum

Nicorette Gum can sometimes cause a slight irritation of the mouth and throat at the start of the treatment. It may also cause increased salivation. The gum may

occasionally stick to dentures and in rare cases damage them.

If you experience any of the following, stop using the gum and seek medical help immediately:

- Swelling of the face, lips, tongue, throat or other parts of the body, wheezing or difficulty breathing or swallowing
- Chest pain, palpitations, an abnormal or fast heart beat
- Pins and needles

Other side-effects include:

Very common side-effects

(*may affect more than 1 in 10 people*):

- headache
- feeling sick (nausea)
- hiccups
- irritation of the throat

Common side-effects

(*may affect up to 1 in 10 people*):

- allergic reactions (swelling of the mouth, lips, throat and tongue, itching of the skin, swelling of skin, ulceration and inflammation of the lining of the mouth).
- cough
- vomiting
- diarrhoea
- burning sensation in the mouth
- taste disturbance or loss of taste
- pins and needles
- dry mouth
- indigestion or excessive gas or wind
- increased salivation
- sore and inflamed mouth
- tiredness (fatigue)
- stomach pain

Uncommon side-effects

(*may affect up to 1 in 100 people*):

- abnormal dreams
- redness or itching of the skin or skin rash
- chest palpitations or fast heart rate or beat
- sudden reddening of the face and/or neck
- high blood pressure
- sudden constriction of the small airways of the lung that can cause wheezing and shortness of breath
- loss or damage to voice
- shortness of breath
- nasal congestion
- sneezing
- throat tightness
- burping (belching)
- swollen, red, sore tongue
- blisters in the mouth
- numbness or tingling of the mouth
- hives (urticaria)
- excessive sweating
- pain in jaw
- aching muscles, muscle tenderness or weakness not caused by exercise
- chest discomfort and pain
- general feeling of discomfort or being unwell or out of sorts (malaise)

Rare side-effects

(*may affect up to 1 in 1000 people*):

- difficulty in swallowing
- decreased feeling or sensitivity, especially in the mouth
- feeling of wanting to be sick (retching)

Side-effects with unknown frequency

- blurred vision, watery eyes
- stomach discomfort
- dry throat, lip pain
- redness of the skin
- muscle tightness

Not known: frequency cannot be estimated from the available data

- Seizure

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via: HPRA Pharmacovigilance, Website: www.hpra.ie. By reporting side-effects you can help provide more information on the safety of this medicine.

5. How to store Nicorette Gum

- Keep the Nicorette Gum out of the sight and reach of children and animals.
- Do not store above 25°C.

- Store Nicorette Freshfruit Gums in original package to protect from light.
- Do not use this medicine after the expiry date which is stated on the carton and blister after “Use before”. The expiry date refers to the last day of that month.
- Dispose of Nicorette Gum sensibly.
- Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away any medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Nicorette Gum contains

Nicorette Gum is available in 3 flavours (classic, freshmint, freshfruit)

Nicorette 4 mg medicated chewing gum contains 4 milligrams (mg) of nicotine (the active ingredient). Other ingredients are: chewing gum, sorbitol, 70% crystallizable sorbitol, anhydrous sodium carbonate, smoking flavor (contains traces of ethanol, cinnamal, cinnamyl alcohol, citral, citronellol, eugenol, geraniol, isoeugenol, limonene, linalool), haverstroo flavour, glycerol 85 percent, quinoline yellow.

Nicorette Freshmint 4 mg medicated chewing gum contains 4 milligrams (mg) of nicotine (the active ingredient). Other ingredients are: chewing gum, xylitol, peppermint essential oil, anhydrous sodium carbonate, acesulfame potassium, levomenthol, light magnesium oxide, quinoline yellow aluminum lake (E104), gum arabic, titanium dioxide (E171), carnauba wax.

Nicorette Freshfruit 4 mg medicated chewing gum contains 4 milligrams (mg) of nicotine (the active ingredient). Other ingredients are: chewing gum, xylitol, peppermint oil, anhydrous sodium carbonate, yellow quinoline lacquer, acesulfame potassium, levomenthol, light magnesium oxide, tutti frutti flavour, hydroxypropylmethylcellulose (HPMC, hypromellose), sucralose, polysorbate 80, quinoline yellow lacquer, acacia, sodium titanium, carnauba wax.

What Nicorette Gum looks like and contents of the pack

The gums are blister packed in sheets of 15. Nicorette Gum (classic) is supplied as 105 pack. Nicorette Freshmint Gum is supplied as 105 pack. Nicorette Freshfruit Gum is supplied as 105 pack.

Parallel Product Authorisation Holder:

IMED Healthcare Ltd, Unit 625, Kilshane Avenue, Northwest Business Park, Ballycoolin, Dublin 15, Ireland.

Manufactured by

McNEIL AB, NORRBROPLATSEN 2, SE-25109 HELSINGBORG, SWEDEN.

Repackaged by

Cast Healthcare Ltd, Unit E, The Business Centre, 5-7 Tobermore Road, Draperstown, Magherafelt, BT45 7AG, UK(NI) or IMED Healthcare Ltd, Unit 625, Kilshane Avenue, Northwest Business Park, Ballycoolin, Dublin 15, Ireland.

For further information on smoking cessation please ring the national smokers quit line on 1800 201 203 or visit www.quit.ie.

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