

nicorette®

2 mg and 4 mg Gum Nicotine chewing gum What you should know about

nicorette® 2 mg Gum
(2 mg nicotine chewing gum)

nicorette® 4 mg Gum
(4 mg nicotine chewing gum)

Please read this leaflet carefully before you start using this medicine. It provides useful information on how to use it safely. Keep the leaflet, you might need it again.

If you think you are having side-effects, have any questions or are not sure about anything please **ask your doctor, nurse or pharmacist.**

1 What the medicine is for

NICORETTE® Gum is a nicotine replacement therapy (NRT). It is used to relieve and/or prevent withdrawal symptoms and reduce the cravings you get when you try to stop smoking, or when cutting down the number of cigarettes you smoke.

NICORETTE® Gum can also be used when you are pregnant or breast-feeding to help you stop smoking, as the risks to your baby are far less than if you continue to smoke. For more information, see *"If you are pregnant or breast-feeding"* section.

Ideally you should always aim to stop smoking. You can use NICORETTE® Gum to achieve this by using it to completely replace all your cigarettes. However NICORETTE® Gum can also be used in other ways,

- if you feel unable to stop smoking completely, or wish to replace certain cigarettes and therefore it can help you to cut down the number of cigarettes you smoke,
- at those times when you can't or do not want to smoke. For example,

- Where you don't want to smoke and avoid harm to others e.g children or family.
- Smoke free areas e.g Pub, work, public transport e.g aeroplanes.

It may also help increase your motivation to quit. When making a quit attempt a behavioural support programme will increase your chances of success.

If you smoke 20 or fewer cigarettes a day, the 2 mg nicotine gum will help relieve your cravings. If you smoke more than 20 cigarettes a day, 4 mg nicotine gum may be more appropriate.

What does nicorette® gum do?

When you stop smoking, or cut down the number of cigarettes you smoke, your body misses the nicotine that you have been absorbing. You may experience unpleasant feelings and a strong desire to smoke (craving). This indicates that you were dependent on nicotine.

When you chew NICORETTE® Gum, nicotine is released and passes into your body through the lining of your mouth. The nicotine released from the gum is sufficient to relieve the unpleasant withdrawal symptoms. It will also help to stop the craving to smoke, but NICORETTE® Gum will not give you the "buzz" you get from smoking a cigarette.

Benefits you can get from using NRT instead of smoking

For the best effect, make sure you chew NICORETTE® Gum correctly. See *"How to chew NICORETTE® Gum – the NICORETTE® Chewing Technique"*.

The benefits of stopping smoking far outweigh any potential risk from using nicotine from NRT. It is the toxins in cigarette smoke such as tar, lead, cyanide and ammonia that cause smoking related disease and death, not the nicotine.

- **You may think that** smoking helps relieve feelings of anxiety and stress, but it does not deal with the cause of the stress and leads to a number of serious diseases. In addition, the feeling of relaxation after smoking is temporary, with withdrawal symptoms and cravings soon returning.

Nicotine replacement therapy can help relieve **nicotine withdrawal symptoms such as irritability, low mood, anxiety, restlessness and cravings** when used in place of cigarettes.

- **NRT may benefit** smokers who want to quit, by helping to control **weight gain** that may be experienced when trying to stop smoking.

Use of NRT is safer than smoking tobacco but as soon as you are ready, you should aim to stop smoking completely.

2 Before using this medicine

⊠ Do not use nicorette® gum:

- **If you are a child under 12 years of age.**
- **if you have an allergy to nicotine** or any of the other ingredients.

⚠ Talk to your doctor, nurse or pharmacist...

- **if you are pregnant or breast-feeding** – you may be able to use nicotine replacement therapy (NRT) to help you give up smoking but you should try to give up without it. See *"If you are pregnant or breast-feeding"* section.
- **if you are in hospital because of heart disease** (including heart attack, disorders of heart rate or rhythm, angina, high blood pressure or stroke). In other heart conditions not requiring you to be in hospital, using NRT is better than continuing to smoke.
- **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 are taking other medicines** such as theophylline, clozapine or ropinirole. Stopping smoking or cutting down may require the dose of these medicines to be adjusted.

➤ **If any of these apply, talk to your doctor, nurse or pharmacist.**

⚠ Some of the ingredients can cause problems

- The chewing gum base contains butylated hydroxy toluene (E321), an anti-oxidant. May cause local skin reactions (e.g. contact dermatitis) or irritation to the eyes and mucous membranes.
- NICORETTE® Gum contains sorbitol. If you have been told by your doctor that you have an intolerance to some sugars, talk to your doctor before taking this medicine.

⚠ If you are pregnant or breast-feeding

If you are pregnant:

1) Firstly, you should try to give up smoking without NRT. Stopping completely is by far the best option. The earlier and quicker you do this the better it is for you and your baby.

2) Secondly, if you can't manage this, you can use NRT as a safer alternative to smoking as the risks to your baby are far less than smoking, however you should talk to your doctor, nurse or pharmacist for advice.

Products that are used intermittently, including NICORETTE® Gum may be preferable to nicotine patches. However, patches may be more suitable if you have nausea or sickness. If you do use patches take them off before going to bed at night.

If you are breast-feeding:

1) Firstly, you should try to give up smoking without NRT.

2) Secondly, if you can't manage this you are best to use NRT products that are taken intermittently (not patches), however you should talk to your doctor, nurse or pharmacist for advice. Breast-feed just before you use NICORETTE® Gum to ensure that the baby gets the smallest amount of nicotine possible.

If you do need to use NRT to help you quit, the amount of nicotine that the baby may receive is considerably smaller and less harmful than the second-hand smoke they would inhale if you smoked. Tobacco smoke produces breathing and other problems in babies and children.

3 How and when to use this medicine

ⓘ 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."* 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 12 years

Do not give this product to children under 12 years.

ⓘ Adults and Children 12 years and over

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

- Use only one piece of gum at a time.
- Do not use more than 15 gums per day.
- The frequency with which you use the gums will depend on how many cigarettes you smoked and how strong they were.

ⓘ 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, inhalator or microtab 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.

1 How to stop smoking:

If you are able to stop smoking you should use NICORETTE® Gum, when needed, in place of cigarettes. As soon as you can (this could be after a number of weeks or months) you should reduce the number of gums you use until you have stopped using them completely.

If you are unable to stop smoking, or do not feel ready to quit at this time, you should replace as many cigarettes as possible with NICORETTE® Gum.

There are toxins in cigarettes that can cause harm to your body. NICORETTE® Gum provides a safer alternative to smoking, for both you and those around you. Reducing the number of cigarettes may also help you to become more motivated to stop smoking. As soon as you are ready you should aim to stop smoking completely.

You can also use NICORETTE® Gum on those occasions when you can't or don't want to smoke e.g. Social situations such as a party, in the pub or when at work.

When making a quit attempt behavioural therapy, advice and support will normally improve the success rate.

If you have quit smoking and want to stop using NICORETTE® Gum but are finding this difficult you should contact your doctor, nurse or pharmacist for advice.

2 If you have used too many gums

If you have used more than the recommended dosage you may experience nausea (feeling sick), 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.

3 If a child has used or swallowed the gums

➤ **Contact a doctor or your nearest hospital Accident and Emergency department immediately** if a child under 12 years uses, chews or swallows this medicine. Take this leaflet and the pack with you.

Nicotine ingestion by a child may result in severe poisoning.

4 Possible side-effects

Like all medicines, NICORETTE® Gum can have side-effects. 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
- lowering of heart rate

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
- hiccuping (due to excessive swallowing of nicotine)

Side-effects of nicorette® gum

NICORETTE® Gum can sometimes cause a slight irritation of the 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 notice any of the following; fast heart rate/beat, abnormal beating of the heart, chest palpitations, shortness of breath or allergic reactions (swelling of the face, mouth,

lips, throat and tongue, itching of the skin, swelling of the skin, ulceration and inflammation of the lining of the mouth, difficulty in breathing and dizziness) stop taking NICORETTE® gum and contact a doctor immediately.

Very common side-effects:

(may affect more than 1 in 10 people):

- headache
- cough
- throat irritation
- (feeling sick) nausea
- hiccups
- sore mouth or throat

Common side-effects:

(may affect up to 1 in 10 people):

- allergic reactions (hypersensitivity)
- dizziness
- taste disturbance or loss of taste
- tingling or numbness of the hands and feet
- stomach pain or discomfort
- diarrhoea
- dry mouth
- excessive gas or wind
- increased salivation
- sore and inflamed mouth
- sickness (vomiting)
- indigestion
- burning sensation in the mouth
- tiredness (fatigue)

Uncommon side-effects:

(may affect up to 1 in 100 people):

- abnormal dream
- 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
- blocked nose, sneezing
- throat tightness
- burping (belching)

- swollen, red, sore tongue
- mouth ulcers or blisters
- numbness or tingling of the mouth
- hives (urticaria)
- excessive sweating
- itching
- rash
- unusual weakness
- jaw-muscle ache
- chest discomfort and pain
- general feeling of discomfort or being unwell or out of sorts (malaise)

Rare side-effects:

(less than 1 in 1,000 people are affected)

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

Other side-effects can include:

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

➤ When you stop smoking you may also develop mouth ulcers. The reason why this happens is unknown.

➤ **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 the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard**

By reporting side-effects you can help provide more information on the safety of this medicine.

You can also report side effects directly in Malta via:

ADR Reporting at: www.medicinesauthority.gov.mt/adrportal

5 Storing and disposal

- **Keep NICORETTE® Gum out of sight and reach of children and animals.** Nicotine in high doses can be very dangerous and sometimes fatal if taken by small children.
- Do not store NICORETTE® Gum above 25°C.
- Do not use the gum after the 'Use before' date on the box or blister strip.
- Dispose of NICORETTE® Gum sensibly.
- Medicines should not be disposed of via waste water or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6 Further information

What's in this medicine?

The active ingredient in NICORETTE® 2 mg Gum is 2 mg Nicotine.

The active ingredient in NICORETTE® 4 mg Gum is 4 mg Nicotine.

Other ingredients are: Chewing gum base, sorbitol, sodium carbonate, flavourings, polacrillin, glycerol and talc.

The chewing gum base contains butylated hydroxy toluene (E321), an anti-oxidant.

The 2 mg gum also contains sodium bicarbonate.

The 4 mg gum also contains quinoline yellow (E104) (yellow colour).

The gum does not contain sugar (sucrose) or animal products.

What the medicine looks like

The gums are blister packed in sheets of 6 or 15 and supplied in packs of packs of 6, 15, 30, 105 or 210 pieces. Not all pack sizes may be marketed.

Who makes nicorette® gum?

The Product Licence holder is McNeil Products Ltd, Maidenhead, Berkshire, SL6 3UG, UK.

The manufacturer is McNeil AB, Helsingborg, Sweden.

This leaflet was revised in June 2017. ®