



# nicorette®

## Freshmint 2 mg and 4 mg Gum

### What you should know about

nicorette® Freshmint 2 mg Gum (2 mg nicotine chewing gum) Low strength  
nicorette® Freshmint 4 mg Gum (4 mg nicotine chewing gum) Full strength  
**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 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.  
To help cut down or quit smoking you should also try to use a behavioural support programme to increase your chances of success. Details of Nicorette ActiveStop are shown at the end of this leaflet.

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.

### 2 Before using this medicine

#### X Do not use Nicorette Gum:

- 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, 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 applies, 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.

#### ▲ If you are pregnant or breast-feeding

**If you are pregnant: ideally, you should try to give up smoking without NRT.** If you can't manage this, you can use NRT 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 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: ideally, you should try to give up smoking without NRT.** 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

#### 1 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.

#### 1 Children under 12 years

Do not give this product to children under 12 years.

#### 1 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.
- Most people use between 8 to 12 gums per day.
- Do not use more than 15 gums per day.
- Children aged 12 up to 18 years should not use for longer than 12 weeks without asking for help and advice from a doctor, nurse or pharmacist.
- Adults aged 18 years and over should not use for longer than 9 months without asking for help and advice from a doctor, nurse or pharmacist.

#### 1 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.

#### 1 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: 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 are an adult you can follow either one of these options. However children should follow the guide to stopping immediately as the recommended duration of nicotine replacement therapy in children is 12 weeks maximum. The only time children should stop gradually is if they are having a problem stopping immediately and they should talk to their doctor, nurse or pharmacist beforehand.

**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 two options which follows.

#### 1 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.

There is a difference in how you stop depending on whether you are aged 12 – 18 years or are 18 years or over. Make sure that you follow the instructions for the age range applicable for you.

#### 1 Adults aged 18 years and over

See the following diagram 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.

Preparation	12 weeks (3 months)	Gradually reduce usage
Step 1	Step 2	Step 3

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

**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.

**Step 3:** Start to reduce the number of gums you use. 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.

- For those using the 4 mg Nicorette gum, the use of 2 mg gums may be helpful when withdrawing from treatment.
- If you need to use the product for longer than 9 months, ask your doctor, nurse or pharmacist for advice.
- 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.

## 1 Children aged 12 years and over

See the following diagram 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.

Preparation	8 weeks	4 weeks
Step 1	Step 2	Step 3

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

**Step 2:** Use the gum for 8 weeks (2 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.

**Step 3:** Reduce the number of gums you use over a period of 4 weeks. 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.

- For those using the 4mg Nicorette gum, the use of 2 mg gums may be helpful when withdrawing from treatment.
- Do not use for longer than 12 weeks in total without asking for help and advice from your doctor, nurse or pharmacist.

## 1 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.

There is a difference in how you stop depending on whether you are aged 12 – 18 years or are 18 years or over. Make sure that you follow the instructions for the age range applicable for you.

## 1 Adults aged 18 years and over

See the following diagram 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.

Preparation	24 weeks (6 months)	12 weeks (3 months)	Gradually reduce usage
Step 1	Step 2	Step 3	Step 4

**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.
- You should aim to stop smoking completely by six months from the beginning of treatment.

**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.

- If you need to use the product for longer than 9 months, ask your doctor, nurse or pharmacist for advice.

## 1 Children aged 12 years and over

Children should follow the guide to stopping immediately. The recommended duration of nicotine replacement therapy in children is 12 weeks maximum. The only time children should stop gradually is if they are having a problem stopping immediately.

Talk to your doctor, nurse or pharmacist before attempting to stop gradually.

## 1 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.

## 1 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 and 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 and hiccupping (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.

### Very common side-effects

(more than 1 in every 10 people are affected): headache, sore mouth or throat, jaw-muscle ache, stomach discomfort, feeling sick (nausea) and hiccups.

### Common side-effects

(less than 1 in every 10 people are affected): dizziness and sickness (vomiting).

### Uncommon side-effect

(less than 1 in every 100 people are affected): hives (urticaria), redness or itching of the skin and chest palpitations.

### Rare side-effects

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

### Very rare side-effects

(less than 1 in 10,000 people are affected): abnormal beating of the heart.

- If you notice these or any other unwanted effects not listed in this leaflet tell your doctor, nurse or pharmacist.
- When you stop smoking you may also develop

mouth ulcers. The reason why this happens is unknown.

## 5 Storing and disposal

- Keep Nicorette Gum out of reach and sight 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 waster 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 Freshmint 2 mg Gum is 2 mg Nicotine

The active ingredient in Nicorette Freshmint 4 mg Gum is 4 mg Nicotine

Other ingredients are: Chewing gum base, xylitol, acesulfame potassium, sodium carbonate, peppermint oil, menthol, polacrillin, magnesium oxide, titanium dioxide E171 (white colour), talc, acacia and carnauba wax. The chewing gum base contains butylated hydroxytoluene (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, 10 or 15 and supplied in packs of 10, 12, 15, 30, 105 and 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 November 2009.

### Information about Nicorette ActiveStop

Nicorette ActiveStop is a personalised support programme which works with Nicorette to support you, with the aim of helping you give up smoking. All you need is internet access and a mobile telephone. Call 0800 244 838 for information

