





## nicorette

4 mg Gum

nicotine chewing gum

Personalised support programme

Enrol on the internet or call now on 0800 244 838.

with



### A guide for users

#### What you should know about

nicorette<sup>®</sup> 4 mg Gum (4 mg nicotine chewing gum) Full strength

nicorette<sup>®</sup> Mint 4 mg Gum (4 mg nicotine chewing gum) Full 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

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# 1 What this 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 in Section 8 of this booklet.

If you smoke more than 20 cigarettes a day, this product will help relieve your cravings.

If you smoke 20 or fewer cigarettes a day, 2 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. Make sure you chew Nicorette Gum correctly to get the hest effect - 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, cvanide and ammonia that cause smoking related disease and death, not the nicotine.

### 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 breastfeeding - 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 page 9 If you are pregnant or breast-feeding.
- 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

Nicorette 4 mg 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. Nicorette Mint 4 mg Gum and Nicorette

- Freshmint 4 mg Gum do not contain sorbitol.
- The chewing gum base contains butylated hydroxy toluene (E321), an antioxidant. 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

## When to use the Nicorette Gums

Following is the dosage information for the Nicorette Gums. 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 on page 15, 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 Nicorette 2 mg Gums are available in alternative packs and should be used if you smoke 20 or fewer cigarettes a day. They can also be used when you gradually start to reduce the strength and number of gums you use each 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.
- 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 of 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 of pharmacist.

#### 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.

### 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 gum 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 follow.

### **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.

### 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.

	12 weeks	Gradually	Time for
Preparation	(3 months)	reduce usage	each step
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" on page 13 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.

- If you need to use the product for longer than 9 months, ask your doctor, nurse or pharmacist for advice.
- ➤The use of 2 mg gums 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.

### 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.

	8 weeks	4 weeks	Time for
Preparation	(2 months)	(1 months)	each step
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" on page 13 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.

- 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.

### **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.

## 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			Gradually reduce usage	for
Step 1	Step 2	Step 3		each step

- 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" on page 13 to decide which strength of gum to use and how often you can take it.

- 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.

- 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.

### 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.

### 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.

### 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
- 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.

Those who suffer from indigestion may suffer from heartburn or indigestion and may benefit from slower chewing and use of the 2 mg gum.

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
- iaw-muscle ache
- stomach discomfort
- feeling sick (nausea)
- hiccups

#### Common side-effects:

(less than 1 in every 10 people are affected)

- dizziness
- sickness (vomiting)

#### **Uncommon side-effects:**

(less than 1 in every 100 people are affected)

- hives (urticaria)
- redness or itching of the skin
- chest palpitations

#### Rare side-effects:

(less than 1 in every 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 away from children and animals.

# 6 Further information

#### What's in this medicine?

The active ingredient is: 4 mg Nicotine.

Other ingredients in Nicorette 4 mg Gum are: Chewing gum base, sorbitol, sodium carbonate, flavourings, polacrilin, glycerol, quinoline yellow (E104) (yellow colour) and talc. The chewing gum base contains butylated hydroxy toluene (E321), an anti-oxidant.

Other ingredients in Nicorette Mint 4 mg Gum are: Chewing gum base, xylitol, sodium carbonate, peppermint oil, menthol, polacrilin, magnesium oxide, quinoline yellow (E104) (yellow colour) and talc. The chewing gum base contains butylated hydroxyl toluene (E321). an anti-oxidant.

Other ingredients in Nicorette Freshmint 4 mg Gum are: Chewing gum base, xylitol, acesulfame potassium, sodium carbonate, peppermint oil, menthol, polacrilin, magnesium oxide, quinoline yellow (E104) (yellow colour), titanium dioxide E171 (white colour), talc, acacia and carnauba wax. The chewing gum base contains butylated hydroxyl toluene (E321), an anti-oxidant.

None of the gums 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 or 12 pieces (Freshmint), 15, 30 or 105 pieces (Original, Mint and Freshmint) or 210 pieces (Original and Freshmint). 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 January 2008. ©

# 7 Helpful tips on giving up

You may have tried to stop smoking before and you know from bitter experience that it's not easy to give up cigarettes. However, you have now taken the first constructive step towards becoming a non-smoker. In

- becoming a non-smoker. In overcoming your tobacco dependence you will have to tackle two problems:
- 1 Your smoking habit.
- 2 Your addiction to nicotine.

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#### Willpower

The overriding success factor in quitting is how determined you are. The first few weeks of quitting or reducing the number of cigarettes you smoke will probably be the most difficult because your smoking ritual is still fresh in your mind.

However, you will find that as time goes by, your willpower becomes stronger. Telling friends, family and work colleagues that you have quit smoking and that you envisage a tough time ahead will encourage them to support you.

#### 1 Pick the right day

There is never a perfect time to give up smoking, but you should plan ahead by choosing a date in the not too distant future on which you are going to give up cigarettes completely, or start reducing the number of cigarettes you smoke. Try to pick a day when you will not be too stressed.

#### 2 Break your routine

For a number of years you will have become accustomed to smoking at certain times, with particular people or in certain situations. Think about the times you will miss smoking the most and plan how you will cope on these occasions. Changing your routine will help you break the habit of smoking.

#### 3 Quit with a friend

Quitting with a fellow smoker is a good idea. It will strengthen your resolve and build on your determination.

Encourage a friend or family member to quit with you. It will give your morale a boost since there will be another person knowing exactly what you're feeling and with whom you can share your resolve to quit smoking.

#### 4 Remove any temptation

To help yourself succeed be sure to remove all cigarettes, matches, lighters etc. from your home, car and work. Ask your friends and colleagues not to offer you cigarettes or smoke close by you but be careful not to offend them. Explain that you have given up. This type of support from friends is of greatest benefit for the first couple of weeks of quitting, as this is your most vulnerable time. The last thing you want is a cigarette close at hand in a moment of weakness.

#### 5 Take one day at a time

When you reach your Quit Day, don't allow yourself to think that you're quitting for good. That will make it seem like a superhuman task. Just promise yourself "I won't have a cigarette today" and take it one day at a time. You'll be surprised how much that little thought helps.

#### 6 Distract yourself

Whenever you feel the urge to smoke coming on, distract yourself by keeping active. Don't feel sorry for yourself. Get up and do something. Do that job around the house or garden that you've been putting off or take up a hobby.

Remember that the craving only lasts a few minutes.

#### 7 Learn to relax

Once you have stopped smoking, taking exercise regularly will not only help you get fitter but will encourage you to relax. Exercise has the ability to relieve stress and tension. Taken regularly it will benefit you physically and psychologically.

If you haven't exercised for some time, take it slowly to begin with and increase the amount of time spent exercising over the course of a few weeks. Not only will exercising help you relax but it also helps to keep your weight under control, which some people find a problem when quitting.

#### 8 Think cash not ash

One of the really noticeable benefits of 'stopping' is the extra cash that's suddenly available. To emphasise the point put the money into a pot marked 'cash not ash' and watch it accumulate. But be sure to use the money to treat yourself. You deserve a reward for not smoking.

#### 9 Dealing with relapses

You might find that in times of stress, reaching for a cigarette is the only thing that will help you through. There may also be certain situations – particularly social situations such as a party or in the pub – where temptation just gets the better of you, so you smoke one or two cigarettes. You might feel that

your only option is to go back to smoking. Don't think of it as having failed, just think through the reasons why you wanted to quit in the first place and don't let those couple of cigarettes get the better of you. Refer back to your plan and start again. You can beat it!

#### 10 If you don't succeed

Giving up is more difficult for some people than others. If you fail to stop first time, don't be disheartened. Try again at a later date – you can do it! Remember the most successful long term ex-smokers have usually had to try several times to stop smoking – if you don't succeed – quit quit again.

#### For further information

Read about Nicorette ActiveStop on the next few pages. This 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.



Personalised support programme

Enrol on the internet or call now on 0800 244 838.

## How can ActiveStop help me?

- Nicorette ActiveStop is an advanced, interactive online programme with mobile phone support. It has been devised by experts and is based on proven scientific principles, to help you give up smoking for good.
- It has been specially designed to be used alongside Nicorette and is on hand 24 hours a day through the internet and your mobile phone.
- Nicorette works with your body to help you deal with the physical craving for nicotine, whilst ActiveStop gives you practical daily support coaching you all the way until you've stopped smoking.

Call now on 0800 244 838.



#### What will I get?

On your personalised ActiveStop web pages you'll have access to:

#### **Diary**

Through a series of daily tasks, we'll guide you through managing your thoughts, feelings and behaviour and how you can plan each day so that you are ready to face whatever arises.

#### **Progress Monitor**

The Progress Monitor brings together all of the headway you are making in one easy-to-view place. From how much money you're saving, to health facts and fitness levels, it will keep you motivated throughout the programme.

#### **Today's Articles**

Daily articles cover a range of topics from the changes your body is undergoing to tips to cope with the inevitable cravings.

#### And the Craving Help-Line

If ever you feel the urge to smoke you can call anytime day or night and by selecting the kind of problem you are experiencing, you'll be able to listen to relevant, on-the-spot advice.

Call now on 0800 244 838.

