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**ActiveStop**

Supporting you, body & mind

Personalised support programme

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

**nicorette<sup>®</sup>**

**nasal spray**

**nicotine**

**nasal spray solution**

with



**ActiveStop**

Supporting you, body & mind

06-0811

# A guide for users

## What you should know about **nicorette**<sup>®</sup> Nasal Spray

(10 ml nasal spray containing nicotine 10 mg/ml)

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.

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# 1 What this medicine is for

**Nicorette Nasal Spray 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.

To help 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.

## What does Nicorette Nasal Spray do?

When you stop smoking, 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.

4 When you spray Nicorette Nasal Spray into your nose,

nicotine passes rapidly into your body through the lining of your nose. The nicotine released is sufficient to relieve the unpleasant nicotine withdrawal symptoms. It will also help to stop your craving to smoke but will not give you the "buzz" you get from smoking a cigarette.

**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.

# 2 Before using this medicine

**X Do not use Nicorette Nasal Spray:**

- 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 page 8 *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 a respiratory disease**, especially asthma.
- **if you have diabetes** – monitor your blood sugar levels more often when starting to use Nicorette Nasal Spray 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 Nasal Spray contains methyl- and propyl parahydroxybenzoate (E216 and E218) which may cause allergic reactions (this may happen after a few days).

## **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, including Nicorette Nasal Spray, 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 Nasal Spray to make sure 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

#### **i** How to use Nicorette Nasal Spray

Follow the instructions and study the pictures below to ensure that you hold the bottle at the correct angle and use Nicorette Nasal Spray correctly.

#### Remove the cap

Remove the protective cap by squeezing the 2 side clips and pulling off the cap as shown in the diagram.

#### Priming the Spray

If you are using Nicorette Nasal Spray for the first time or if you have not used the spray for 2-3 days



you must first prime the spray pump. (Please note priming reduces the number of doses you may get from a bottle).

- 1 Point the spray safely away from you and any other adults, children or pets that are near you.
- 2 Place the nozzle between your first and second finger with your thumb on the bottom of the bottle.
- 3 Press several times firmly and quickly until a fine spray appears (up to 7-8 strokes).

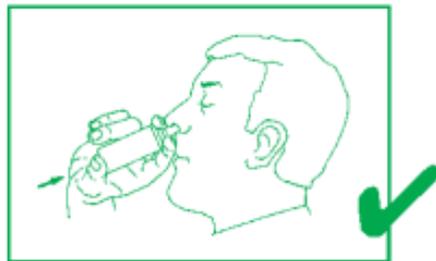


#### Using the Spray

- 1 Insert the spray tip into one nostril, pointing the top towards the back of your nose. Press firmly and quickly. Then, insert the spray tip into your other nostril and



repeat the process. See the diagrams which show the correct and incorrect way of inserting the spray.



### After Using the Spray

- 1 Replace the protective cap.
- 2 Keep the spray out of the reach of children and animals.
- 3 The spray should be stored protected from light.

### **i** When to use Nicorette Nasal Spray

The dosage information for Nicorette Nasal Spray follows. This shows when you should take the nasal spray, the maximum number of sprays you can have a day and how long you can continue to use the spray for. Please read the information carefully and then go to the "How to stop smoking" section which shows you how to give up smoking.

- Use Nicorette Nasal Spray whenever you feel the urge to smoke. The frequency with which you use the spray will depend on how many cigarettes you smoked and how strong they were. You can use one spray in each nostril up to twice an hour. You may find you need less.
- Each spray delivers 50 microlitres of solution, which contains 0.5 mg of nicotine.
- The 10ml bottle contains enough solution to deliver about 200 sprays.
- You may find that in the first few days of use the spray may irritate your nose and make you sneeze and your eyes water. If this occurs do not drive or operate machinery until these unwanted effects have stopped.

### **i** Children under 12 years

Do not give this product to children under 12 years.

## **i** Adults and Children aged 12 years and over

Age	Dose
Adults and Children aged 12 years and over	One spray in each nostril up to twice an hour to relieve cravings.

- Do not spray in each nostril more than twice in one hour.
- Do not use more than 64 sprays per day – this is equivalent to 2 sprays in each nostril every hour for 16 hours.
- Children aged 12 and up to 18 years should not use for longer than 12 weeks in total 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 in total without asking for help and advice from a doctor, nurse or pharmacist.

## **i** How to stop smoking

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.

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

If you feel that you need extra help or want to use an additional NRT product, talk to your doctor, nurse or pharmacist as they will be able to advise you.

## **i** Stopping Immediately

The idea is to stop smoking immediately and use the nasal spray to relieve the cravings to smoke. After

achieving this you then stop using the spray. The timescale is up to 12 weeks (3 months) in total.

### **i** Adults and children aged 12 years and over

See the following diagram which shows the basic step by step process. Make sure that you read the instructions for each step in the information which follows.

	8 weeks (2months)	2 weeks	2 weeks	Time taken for each step
Preparation				
Step 1	Step 2	Step 3	Step 4	

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

**Step 2:** Use Nicorette Nasal Spray to relieve your cravings to smoke for 8 weeks. See Dosage section on page 14 to decide how many sprays you are allowed to use and how often you can use the nasal spray.

**Step 3:** Start reducing the number of sprays you use over 2 weeks. By the end of two weeks you should aim to have halved the number of sprays you use each day.

**Step 4:** Cut the number to none at all over the following 2 weeks.

- In step 3 & 4 of the course you may find that one spray to one nostril will help you to begin to reduce the number of sprays you need to use.
- You should not use Nicorette Nasal Spray continuously for longer than 3 months.
- You might feel a sudden craving to smoke long after you have given up smoking and stopped using Nicorette Nasal Spray. Remember you can use Nicorette Nasal Spray again if this should happen.
- If you need to use this product for more than 9 months in total, you should ask your doctor, nurse or pharmacist for advice.

### **If you have used too much Nasal Spray**

If you have used more than the recommended dosage of Nicorette Nasal Spray or have smoked whilst using Nicorette Nasal Spray, you may experience nausea, 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 Nasal Spray**

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

Nicotine inhalation or ingestion by a child may result in severe poisoning.

## **4 Possible side-effects**

Like all medicines, Nicorette Nasal Spray 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 Nasal Spray 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

### Side-effects of Nicorette Nasal Spray

During the first 2 days of treatment, many people experience nasal irritation such as sneezing, running nose, watering eyes and cough. If you continue to use the nasal spray, the severity of these effects and how often they occur will reduce.

### Very common side-effects:

*(more than 1 in every 10 people are affected)*

- runny nose
- sneezing

- watery eyes
- nosebleeds

### Common side-effects:

*(less than 1 in every 10 people are affected)*

- headache
- dizziness
- cough
- stomach discomfort
- feeling sick (nausea)
- sickness (vomiting)

### Uncommon side-effects:

*(less than 1 in every 100 people are affected)*

- chest palpitations

### 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 Nasal Spray out of the reach and sight of children and animals.** Nicotine in high doses can be very dangerous and sometimes fatal if taken by small children.
- Store Nicorette Nasal Spray protected from light.
- Do not use Nicorette Nasal Spray after the 'Use before' date shown on the carton or label.
- Dispose of Nicorette Nasal Spray sensibly.

## 6 Further information

### What's in this medicine?

The active ingredient is: Nicotine.

Other ingredients are: Disodium phosphate, sodium dihydrogen phosphate, sodium chloride, citric acid, polysorbate 80,  $\beta$ -ionone, methyl and propyl parahydroxybenzoate (E216 and E218), disodium edetate and water.

### What the medicine looks like

Nicorette Nasal Spray consists of a glass bottle of solution, attached to a pump spray unit designed to be put into your nose. A protective cap which covers the nozzle is also supplied

### Who makes Nicorette Nasal Spray?

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 July 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 overcoming your tobacco dependence you will have to tackle two problems:

- 1 **Your smoking habit.**
- 2 **Your addiction to nicotine.**

### Willpower

The overriding success factor in quitting is how determined you are. The first few weeks of quitting 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. This is your Quit Day. 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.

## 8 Nicorette Activestop



# ActiveStop

Supporting you, body & mind

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.**

