

# nicorette<sup>®</sup> nasal spray

nicotine  
nasal spray solution



618609

## **A guide for users**

### **What should you know about**

#### **nicorette® 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. The information applies only to this product. If you have any questions, or you are not sure about anything, please ask your doctor, nurse or pharmacist.

**Remember:** This medicine is for you. Never give it to others. It may harm them even if their symptoms are the same as yours.

#### **What is Nicorette Nasal Spray?**

Each spray of Nicorette Nasal Spray delivers 0.5 milligram of nicotine, the active ingredient, into the nostril.

Other ingredients in Nicorette Nasal Spray are: disodium phosphate, sodium dihydrogen phosphate, sodium chloride, citric acid, polysorbate 80,  $\beta$ -ionone (aroma), methyl and propyl parahydroxybenzoate (E216 and E218 - preservatives), disodium edetate (stabiliser) and water. Nicorette Nasal Spray consists of a glass bottle of solution, attached to a pump spray unit designed to be put into your nose. The solution is sufficient to deliver about 200 sprays from each bottle.

#### **Who makes Nicorette Nasal Spray?**

Nicorette Nasal Spray is made by Pfizer Health AB, Helsingborg, Sweden.

The Marketing Authorisation is held by Pharmacia Limited, Ramsgate Road, Sandwich, Kent, CT13 9NJ, UK.

#### **What is Nicorette Nasal Spray used for?**

Nicorette Nasal Spray is a nicotine replacement therapy (NRT). It is used to relieve withdrawal symptoms and to reduce the cravings for

nicotine that people get when they stop smoking.

### **What does Nicorette Nasal Spray do?**

When you stop smoking, your body misses the nicotine that you have been absorbing from the tobacco smoke. You may experience unpleasant feelings and a strong desire to smoke ('craving'). This shows that you were dependent on nicotine. However, it is the toxins in cigarette smoke such as tar, lead, cyanide and ammonia that cause smoking related disease and death, rather than the nicotine. The benefits of stopping smoking far outweigh any potential risk from using nicotine from NRT.

When you spray Nicorette Nasal Spray into your nose, nicotine passes rapidly into your body through the lining of your nose. The nicotine absorbed is sufficient to relieve the unpleasant nicotine withdrawal symptoms. It will also help to stop the craving to smoke, but Nicorette Nasal Spray will not give you the "buzz" you get from a cigarette. Make sure you use Nicorette Nasal Spray correctly to get the best effect - see 'How to use Nicorette Nasal Spray'.

As well as the effects of nicotine, you could be very attached to the habit of smoking. For example lighting up after a meal or in certain situations or when you are with particular people. These rituals are part of your smoking habit which you may have had for many years. To succeed in giving up you should try to avoid situations where you may be tempted to smoke. Think about the times when you are most likely to miss smoking and try to plan how you will cope on these occasions. Changing your routine will help you to break the habit of smoking.

Encouragement and support from your doctor, nurse, pharmacist, friends and family can make giving up less stressful and more successful. For professional advice about giving up smoking ask your doctor, nurse or pharmacist.

### **Do not use Nicorette Nasal Spray if:**

- you have an allergy to nicotine or any of the other ingredients in the Nicorette Nasal Spray.

### **Before you use Nicorette Nasal Spray**

There are some circumstances (listed below) where you should consult

your doctor, nurse or pharmacist before using Nicorette Nasal Spray:

- if you are pregnant or breast-feeding - you should try to give up smoking without the use of nicotine replacement therapy (see 'What if you are pregnant or breast-feeding?').
- if you have heart disease (including heart attack and disorders of heart rate and/or rhythm) or have suffered a stroke for which you are in hospital. In other heart conditions not requiring you to be in hospital, using NRT is better than continuing to smoke.
- if you have high blood pressure that is not adequately controlled by treatment.
- if you have a stomach or duodenal ulcer and/or inflammation of the oesophagus (passage between the mouth and stomach).
- if you have serious liver or kidney disease.
- if you have a respiratory disease, especially asthma.
- 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 - you should monitor your blood sugar levels

more often when starting to use Nicorette Nasal Spray as you may find your insulin/medication requirements alter.

- if you are taking any other medicines such as theophylline, clozapine or ropinirole. Stopping smoking may require the dose to be adjusted.

Nicorette Nasal Spray contains methyl- and propyl parahydroxybenzoate (E216 and E218) which may cause allergic reactions (possibly delayed).

#### **What if you are pregnant or breast-feeding?**

##### **Pregnancy**

Smoking during pregnancy is associated with risks such as poor growth of the baby before birth, premature birth or stillbirth. Stopping smoking is the single most effective intervention for improving both your health and that of your baby and the earlier smoking stops the better.

Ideally, stopping smoking during pregnancy should be achieved without NRT. However if you have tried and this is not possible, NRT may be recommended to help as the risk to the developing baby is less

than that expected from continued smoking. The decision to use NRT should be made as early on in the pregnancy as possible with the aim of discontinuing use as soon as possible.

Products that are used intermittently may be preferable to nicotine patches. However, patches may be preferred if you have nausea or sickness. Patches, if used, should be removed before going to bed at night.

### **Breast-feeding**

Tobacco smoke produces breathing and other problems in babies and children. If you 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 otherwise be breathing in. You are best to use NRT products that are taken intermittently (i.e. not patches) and try to breast-feed at a time just before you use the product to ensure that the baby gets the smallest amount of nicotine possible.

### **When to use Nicorette Nasal Spray and for how long?**

#### **Adults over 18 years of age**

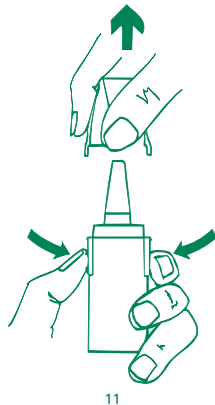
Because smoking is an addiction, you may find it difficult to give up. From time to time you may still have strong urges to smoke but if you follow these recommendations, you have a good chance of quitting.

- Pick a start day when you will not be too stressed and stop smoking.
- Use Nicorette Nasal Spray whenever you feel the urge to smoke.

### 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:

1. Remove the protective cap.



2. 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.

Point the spray safely away from you and any other adults, children or pets near you.

Place the nozzle between your first and second finger with your thumb on the bottom of the bottle.

Press several times firmly and quickly until a fine spray appears (up to 7-8 strokes).



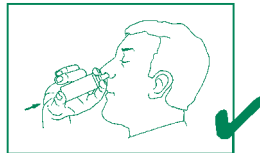
3. Insert the spray tip into one nostril, pointing the top towards the back of your nose. Press firmly and quickly. Then, insert the spray tip into your other nostril and repeat the process.

4. Replace the protective cap.

5. You may find that for the first few days of use, Nicorette Nasal Spray irritates your nose making you sneeze and your eyes may water. If this occurs do not drive or operate machinery until these unwanted effects have stopped.

6. 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.

7. You should not use more than 64 sprays in any period of 24 hours. This is equivalent to using one spray into each nostril twice an hour for 16 hours. Do not exceed the stated dose.





You should use Nicorette Nasal Spray to relieve your cravings to smoke for eight weeks. After eight weeks you should aim to gradually reduce your use of Nicorette Nasal Spray. Over the next two weeks reduce the number of times you use Nicorette Nasal Spray each day by half, and over the following two weeks reduce your use until you have stopped using it altogether. Towards the end of the course you may find that one spray to one nostril only is sufficient. You should try not to 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 the product for longer than 9 months, ask your doctor, nurse or pharmacist for advice.

### **Children over 12 years**

Follow the dosage instructions above for adults over 18 years of age. Children over 12 years should only use NRT for up to 12 weeks. If you need to use this medicine for longer than 12 weeks, consult your doctor, nurse or pharmacist for advice.

**Do not give to children under 12 years.**

### **What should you do if you have used too much Nicorette Nasal Spray?**

If you have used more than the recommended numbers of sprays 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 any unwanted effects occur, contact a doctor or your nearest hospital Accident and Emergency Department immediately. If you go to a doctor or hospital, take this leaflet and the pack with you.

### **What should you do if a child has used or swallowed Nicorette Nasal Spray?**

If a child under 12 years has used or swallowed Nicorette Nasal Spray contact a doctor or your nearest hospital Accident and Emergency Department immediately. If you take the child to the doctor or hospital, take this leaflet and the pack with you.

### **Are there any unwanted effects from Nicorette Nasal Spray?**

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.

The majority of people using the Nicorette Nasal Spray for the first time find that it may cause sneezing, coughing, a runny nose or watery eyes. It is important not to use Nicorette Nasal Spray whilst driving or operating machinery. These effects may be quite unpleasant at first. However after a few days when you become accustomed to Nicorette Nasal Spray these unwanted effects will gradually disappear. If you feel faint or sick or get headaches you may be taking in too much nicotine.

Other commonly reported side-effects include nosebleeds, headache,

dizziness, stomach discomfort, nausea and vomiting. Chest palpitations have also occurred but reports of this are uncommon.

Very rarely abnormal beating of the heart has been reported.

If you develop palpitations, an uneven (irregular) heart beat or bad indigestion, do not use Nicorette Nasal spray, do not smoke and contact a doctor immediately.

You may experience some unwanted effects because by stopping smoking you have reduced the amount of nicotine you are taking. These effects are nicotine withdrawal symptoms and include irritability/aggression, feeling low, anxiety, restlessness, poor concentration, increased appetite/weight gain, urges to smoke ('craving'), night-time awakenings/sleep disturbance and lowering of your heart rate. You may experience these effects if you under use Nicorette Nasal Spray before you are ready to reduce your nicotine intake.

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

If you notice these or any other unwanted effects not listed in this leaflet tell your doctor, nurse or pharmacist.

If you find it difficult to reduce the number of sprays you are using, or to stop using Nicorette Nasal Spray altogether, or are worried that without it you will start smoking again, talk to your doctor, nurse or pharmacist.

Remember, Nicorette Nasal Spray is not intended as a substitute for smoking, it is an aid to giving up.

#### **Taking care of Nicorette Nasal Spray**

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

#### **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**

Please read the attached leaflet, 'We'll Help You Make a Fresh Start', which contains details of the 'Nicorette® Fresh Start Complete Quitter's Support Programme'.

### **Date of preparation of this leaflet:**

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**nicorette**<sup>®</sup>

**Fresh Start**  
Complete Quitter's Support Programme

**PHARMACIA**

Pharmacia Limited, Ramsgate Road,

Sandwich, Kent, CT13 9NJ, UK.

Contains nicotine. Always read the label.

Requires willpower.