

nicorette®

nasal spray
nicotine
nasal spray solution

What you should 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. 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 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.

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.

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

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 “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 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

① 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.

Care should be taken not to spray the eyes whilst administering NICORETTE® Nasal Spray

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

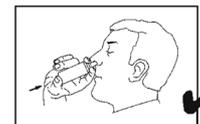
If you are using NICORETTE® Nasal Spray for the first time or if you have not used the spray for 2-3 days you must first prime the spray pump. (Please note priming reduces the number of doses you may get from a bottle).

- 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.

① 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.

① Children under 12 years

Do not give this product to children under 12 years.

① Adults and Children aged 12 years and over

Age	Dose
Adults and Children 12 years and over aged	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.

① 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.

1 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.

1 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.

Preparation	8 weeks (2 months)	2 weeks	2 weeks	Time taken for each step
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 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.

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® Nasal Spray and contact a doctor immediately.

Very common side-effects:

(may affect more than 1 in 10 people):

- runny nose

Common side-effects:

(may affect up to 1 in 10 people):

- headache
- dizziness
- tingling or numbness of the hands and feet
- cough
- nose bleeds
- throat irritation
- feeling sick (nausea)
- sickness (vomiting)
- excessive sweating
- itching
- rash
- chest discomfort and pain

Uncommon side-effects:

(may affect up to 1 in 100 people):

- abnormal dream
- allergic reactions (hypersensitivity)
- sudden reddening of the face and/or neck
- high blood pressure
- tiredness (fatigue)
- general feeling of discomfort or being unwell or out of sorts (malaise)

Other side-effects can include:

- watery eyes
- fast heart rate/beat
- nasal discomfort
- throat discomfort and pain
- sneezing
- stomach discomfort
- redness of the skin
- hives (urticaria)
- unusual weakness

➤ 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.

5 Storing and disposal

■ **Keep NICORETTE® Nasal Spray out of the sight and reach 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.

■ 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 is: Nicotine.

Other ingredients are: Disodium phosphate, sodium dihydrogen phosphate, sodium chloride, citric acid, polysorbate 80, β-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 2017. ©