

Information for the user



NicAssist 10 mg/ml Nasal Spray (Nicotine)

Read all of this leaflet carefully because it contains important information for you.

This medicine is available without prescription to help you stop smoking. However, you still need to use it carefully to get the best results from it.

- Keep this leaflet, you may need to read it again
- Ask your pharmacist if you need more information or advice
- 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 must talk to a doctor if you do not feel better or if you feel worse

What this medicine is for

This medicine contains nicotine which belongs to a group of medicines called nicotine replacement therapy or NRT. It acts to substitute the nicotine that you normally get from cigarettes and can help you stop smoking.

It can be used to relieve the symptoms of nicotine withdrawal and reduce the cravings for nicotine that you may get when you try to stop smoking.

To help you quit smoking you should also try to use a behavioural support programme to increase your chances of success.

When you stop smoking, your body misses the nicotine that you have been getting from the smoke. You may experience unpleasant feelings and a strong desire to smoke ("craving"). This shows that you were dependent on nicotine.

When you use the nasal spray, nicotine passes rapidly into your body through the lining of your nose. The nicotine is sufficient to relieve the unpleasant withdrawal symptoms. It will also help to stop your craving to smoke but will not give you the "buzz" you get from 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.

Before you use this medicine

This medicine can be used by adults and children of 12 years and over. However, some people should not use this medicine or should seek the advice of their pharmacist or doctor first.

X Do not use:

- **If you are allergic** to any of the ingredients in this medicine (see "**What is in this medicine**")

! Talk to your pharmacist, nurse or doctor:

- If you are in hospital because of heart disease (e.g. heart attack, problems with your heart rate or rhythm, stroke, angina or high blood pressure) – try to give up smoking first without using NRT. However, once you are out of hospital, if you still need help to stop smoking, you can use this medicine. For other heart conditions that do not require you to be in hospital, using NRT is better than continuing to smoke

- If you have diabetes – monitor your blood sugar levels more often when you start using this medicine. You may find that you need to adjust the amount of insulin you use, or the amount of tablets you take (ask your doctor or diabetes nurse about this)
- If you have an ulcer in your stomach or upper intestine or problems such as pain or swelling of the stomach or oesophagus (the passage between your mouth and stomach)
- If your liver or kidneys do not work properly
- If you have asthma or other lung problems
- If you have an overactive thyroid gland
- If you have high blood pressure due to a tumour near your kidney (your doctor may have told you that you have a condition called phaeochromocytoma)
- If you are taking other medicines regularly prescribed by your doctor (see “**If you take other medicines**”)
- If you are pregnant or breastfeeding (see “**Other important information**”)

Other important information

If you are pregnant: You should try to stop smoking without using NRT.

However, if you still need help to stop smoking, you can use this product as the risk to your baby is far less than if you continue to smoke. You should talk to your pharmacist, nurse or doctor for more advice.

NRT products that are used intermittently, such as this one, may be preferable to nicotine patches. However, if you feel sick or are sick (morning sickness) the patches may be better for you. If you do use nicotine patches they should be taken off before bedtime.

If you are breastfeeding: You should try to stop smoking without using NRT.

However, if you still need help to stop smoking, you should use NRT products that are used intermittently, not patches. You should talk to your pharmacist, nurse or doctor for more advice.

Breastfeeding your baby just before you use the nasal spray makes sure that your baby gets the smallest amount of nicotine possible.

The amount of nicotine that your baby may receive when you are using the nasal spray or other NRT products is much smaller and less harmful than the second-hand smoke they would inhale if you smoked.

Tobacco smoke causes breathing and other health problems in babies and children. If your husband, partner or other family members smoke too, try to get them to give up with you.

Driving and using machines: The nasal spray may irritate your nose and may make you sneeze or make your eyes water when you first start using the spray. Do not drive or use machines until you are sure you are not affected.

Nicotine products and children: Nicotine can be very dangerous to children. The amount of nicotine tolerated by adults and adolescents can make children very ill, and can sometimes be fatal. Do not leave your nasal spray where children may get hold of it.

Some of the ingredients can cause problems: Methylparahydroxybenzoate (E218) and propylparahydroxybenzoate (E216) in this medicine may cause allergic reactions (possibly delayed).

If you take other medicines

Before you use this medicine, make sure that you tell your pharmacist about ANY other medicines you might be using at the same time, particularly the following:

- Theophylline, clozapine, ropinirole – your doctor may want to monitor the amount of medicine that you take

When you stop smoking or cut down, your metabolism slows down. This can mean that

some medicines may stay in your body longer than usual.

If you take any medicine on a regular basis, tell your doctor that you intend to stop smoking and follow his or her advice about these other medicines.

✓ How and when to use this medicine

When to use the nasal spray

Read all of the following information carefully before starting to use the nasal spray:

- Follow the instructions in the table. The table shows how many sprays you should be using and when and how you should use the nasal spray. It also shows you the maximum amount of time you should be using nicotine replacement therapy (NRT) for
- Use the 'How to use the nasal spray' instructions to make sure that you use the nasal spray correctly to release the nicotine
- For information on how to stop smoking using the nasal spray, go to 'How to stop smoking' Use the nasal spray when you feel the urge to smoke. The number of sprays you use each day will depend on how many cigarettes you smoked and how strong they were.
- You can use one spray in each nostril up to twice in an hour but you may find you need to use less than this
- Each spray delivers 500 micrograms of nicotine in 50 microlitres of solution. Each bottle contains enough solution to deliver approximately 200 sprays

! The nasal spray may irritate your nose and may make you sneeze or make your eyes water when you first start using the spray.

! Take care to avoid the eyes when you are using the spray.

Adults and children of 12 years and over:

Age	How many sprays and when to use
Adults and children of 12 years and over	One spray in each nostril as required to relieve cravings. Don't use more than twice an hour.
<p>Don't use more than 64 sprays per day. This is equivalent to using 2 sprays in each nostril every hour for 16 hours.</p> <p>Children and adolescents of 12 to 17 years should not use for longer than 12 weeks without asking for help and advice from a pharmacist, nurse or doctor.</p> <p>Adults of 18 years and over should not use for longer than 9 months in total without asking for help and advice from a pharmacist, nurse or doctor.</p>	

How to use the nasal spray

Read all of the following instructions carefully before starting to use the nasal spray.

You need to hold the bottle and use the spray correctly to ensure that nicotine is delivered correctly.

Directions for using the spray

1. Remove the protective dust cap by squeezing the 2 side clips and pulling the cap off.
<Pictogram of how to remove cap>
2. A new spray, or one which has not been used for 2-3 days, may not work the first time and must be "primed" (priming reduces the number of sprays you may get from a bottle).
<Pictogram of how to prime the spray>
 - Point the spray away from you and any other adults, children or pets that are near you
 - Put your forefinger and middle finger on the collar either side of the nozzle and

your thumb underneath the bottle

- Keeping your thumb still, press down firmly and quickly with your fingers to pump the spray until a fine spray appears (up to 7-8 strokes)
- Never try to unblock or enlarge the tiny spray hole with a pin or other sharp object because this may damage the spray mechanism

3. Hold the spray as described for priming the spray.
4. Insert the tip of the spray into one nostril pointing the tip towards the back of your nose NOT straight up your nose. Press down with your fingers firmly and quickly. Then insert the tip of the spray into your other nostril and repeat the process if required.
<pictogram of correct use of the spray in the nose>
5. After using the spray wipe the spray nozzle with a clean tissue and then replace the protective cap. Store the spray out of the sight and reach of children and animals and protect from light.

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 the nasal spray, you are worried that you will start smoking again without it or you find it difficult to reduce the number of sprays you are using, talk to your pharmacist, nurse or doctor.

Remember the nasal spray is not intended as a substitute for smoking, it is an aid to giving up.

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. You should aim to stop using the nasal spray within 12 weeks (3 months).

Adults of 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 you read the instructions for each step in the information which follows.

Preparation	8 weeks (2 months)	2 weeks	2 weeks
Step 1	Step 2	Step 3	Step 4

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

Step 2: **Use the nasal spray for up to 8 weeks (2 months) to relieve your cravings.** See the table to see how many sprays you should be using and when and how you should use the nasal spray.

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

Step 4: **Cut the number of sprays to none at all** over the next two weeks.

- ! You may find that using one spray in just one nostril may help you to begin to reduce the number of sprays you need to use in steps 3 and 4.

You should not use Boots NicAssist 10 mg/ml Nasal Spray continuously for more than 3 months.

You might feel a sudden craving to smoke long after you have given up smoking and stopped using Boots NicAssist 10 mg/ml Nasal Spray. Remember you can use nicotine

replacement therapy again if this should happen.

If you need to use this product for more than 9 months in total, you should ask your pharmacist, nurse or doctor for advice.

Children and adolescents of 12 to 17 years

Children and adolescents can follow the same method as adults, however they should not use NRT for longer than 12 weeks without asking for help and advice from a pharmacist, nurse or doctor.

! **If you use too many sprays:** You may get the following symptoms – feeling sick, salivation, pain in your stomach, diarrhoea, sweating, headache, dizziness, hearing disturbance, weakness.

If this happens contact a doctor or hospital casualty department straight away. Take the medicine and this leaflet with you.

If a child under 12 accidentally uses or swallows some of this medicine take them to casualty immediately. Take the medicine and this leaflet with you. Nicotine ingestion by a child may cause severe poisoning.

Possible side effects

Most people can use this medicine without any problems but sometimes you may notice some side effects. Many of these effects are due to nicotine, they may also happen when you smoke.

! **If you notice any of the following serious side effects, stop using the medicine, do not smoke and see your doctor as soon as possible:**

- You develop a fast, slow or irregular heart beat
- You have an allergic reaction to the nasal spray such as rash, itching or swelling of the tongue, mouth or throat (go straight to casualty if severe)

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 use too few sprays before you are ready to reduce your nicotine intake.

These effects include:

- Irritability or aggression, feeling low, anxiety, restlessness
- Poor concentration, urges to smoke (craving), night time awakening or sleep disturbance
- Increased appetite or weight gain
- Lowering of heart rate

Effects of too much nicotine

You may also get these effects if you are not used to inhaling tobacco when you smoke. You may be able to relieve these effects by using the sprays less often.

These effects include:

- Feeling faint, feeling sick (nausea), headache

Side effects of the nasal spray

During the first 2 days of using the nasal spray, many people may get irritation of the nose such as sneezing, runny nose, watering eyes or a cough. If you continue to use the spray these effects and how often you may get them will reduce.

Very common side effects: (more than 1 in every 10 people are affected)

- Runny nose

Common side effects: (less than 1 in every 10 people are affected)

- Headache, dizziness, pins and needles
- Palpitations
- Cough, throat irritation, shortness of breath, nose bleeds
- Feeling sick, being sick
- Itching, skin rash, excess sweating
- Chest pains

Uncommon side effects: (less than 1 in every 100 people are affected)

- Abnormal dreams
- Allergic reactions
- Flushing, high blood pressure
- Feeling tired or unwell

Very rare side effects: (less than 1 in 10,000 people are affected)

- Abnormal beating of the heart

Side effects with unknown frequency:

- Severe allergic reaction, swelling or redness of the skin, hives
- Watery eyes, nose discomfort, sneezing, discomfort and pain in the mouth and throat
- Stomach discomfort
- Changes in heart rhythm (you may notice a fast heart rate or beat)
- Feeling weak

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

Reporting side effects

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.

How to store and dispose of this medicine

Store the nasal spray protected from light.

Keep this medicine in a safe place out of the sight and reach of children and animals, preferably in a locked cupboard.

Nicotine in high amounts can be very dangerous and sometimes fatal if used or swallowed by small children.

Use by the date on the label edge or the end flap of the carton. After this date return any unused product to your nearest pharmacy for safe disposal.

Medicines should not be disposed of via waste-water or household waste. These measures will help to protect the environment.

What is in this medicine

This pack contains one 10 ml nasal spray containing 10 mg/ml of nicotine in a solution to deliver approximately 200 sprays. Each spray delivers 500 micrograms of nicotine in 50 microlitres of solution.

As well as the active ingredient, the spray also contains disodium phosphate, sodium dihydrogen phosphate, sodium chloride, citric acid, polysorbate 80, β -ionone,

methylparahydroxybenzoate (E218), propylparahydroxybenzoate (E216), disodium edetate, purified water.

Who makes this medicine

This product is manufactured for The Boots Company PLC Nottingham NG2 3AA by McNeil AB Helsingborg Sweden.

The Marketing Authorisation holder is McNeil Products Ltd Maidenhead Berkshire SL6 3UG. Leaflet prepared December 2015.

If you would like any further information about this product, please contact The Boots Company PLC Nottingham NG2 3AA

Other formats

To request a copy of this leaflet in Braille, large print or audio please call, free of charge:

0800 198 5000 (UK only)

Please be ready to give the following information:

Product name: Boots NicAssist 10 mg/ml Nasal Spray

Reference Number: 15513/0180

This is a service provided by the Royal National Institute of Blind People.

Helpful tips about giving up smoking

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 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 are stopping 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. 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 circumstances. 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 determination to quit smoking.

4 Remove any temptation

To help yourself succeed, be sure to remove all cigarettes, matches, lighters etc. from the home, the car, and at 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 Keep active

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 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

After you have stopped smoking 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 – 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 again.