



NicAssist 15 mg Inhalator (Nicotine)

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

This medicine is available without prescription to help relieve and/or prevent cravings for nicotine when you are trying to give up smoking or for when you can't or don't want to smoke cigarettes. However, you 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

What this medicine is for

This medicine contains nicotine which belongs to a group of medicines called nicotine replacement therapy (NRT). It acts to substitute the nicotine that you normally get from cigarettes and can be used to relieve and/or prevent cravings for nicotine when you are stopping smoking, cutting down or when you can't or don't want to smoke cigarettes.

It can be used to relieve the symptoms of nicotine withdrawal and to relieve and/or prevent the cravings for nicotine that you get:

- When you stop smoking completely
- When you cut down on the number of cigarettes you smoke while you try to give up
- If you feel unable to stop smoking but you don't want to smoke cigarettes or you want to avoid causing harm to others, such as when you are with friends or family, or
- If you feel unable to stop smoking completely but you can't smoke cigarettes, such as when you are at a party, in the pub, at work, on a plane or train etc.

This medicine can also be used when you are pregnant or breastfeeding to help you stop smoking, as the risk to your baby when using this product is far less than if you continue to smoke. For more information see "Other important information".

When you stop smoking, cut down, or you can't or don't want to smoke cigarettes, 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 are dependent on nicotine. When you use the inhalator, nicotine is released and passes into your body through the lining of your mouth. The nicotine is sufficient to relieve and/or prevent the unpleasant withdrawal symptoms. It will also help to relieve and/or prevent your craving to smoke but will not give you the "buzz" you get from a cigarette.

You should always aim to stop smoking completely whilst using the inhalator. To help you cut down or stop smoking completely you should also try to use a behavioural support programme to increase your chances of successfully stopping smoking.

Benefits you can get from using NRT instead of smoking

For the best effect, ensure that you use Boots NicAssist Inhalator correctly – see "How to use the inhalator".

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.**

- **You may think that** smoking helps relieve feelings of anxiety and stress, but it does not deal with the cause of the stress and leads to a number of serious diseases. In addition, the

feeling of relaxation after smoking is temporary, with withdrawal symptoms and cravings soon returning

Nicotine replacement therapy **can help relieve nicotine withdrawal symptoms such as irritability, low mood, anxiety, restlessness and cravings** when used in place of cigarettes.

- **NRT may benefit** smokers who want to quit, by helping to **control weight gain** that may be experienced when trying to stop smoking

Use of NRT is safer than smoking tobacco but as soon as you are ready, you should aim to stop smoking completely.

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**”)
- **If you are a child under 12 years of age**

! 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 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 have long term throat problems or difficulty breathing due to bronchitis (a condition which produces lots of phlegm on the chest), emphysema or asthma – the inhalator may not be suitable for you to use and you may be advised to use a different type of NRT (ask your pharmacist about other NRT products such as patches, gums, lozenges, microtabs)
- If you have ever experienced seizures (fits)
- If you are pregnant or breastfeeding (see “**Other important information**”)

Choking risk: This product contains small cartridges, which could be a choking hazard if a child attempts to swallow one. Keep any unused cartridges in the pack out of the sight and reach of children.

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 inhalator 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 inhalator 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.

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 inhalator or cartridges where children may get hold of them.

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 reduce the amount of cigarettes you smoke, 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 or reduce the amount of cigarettes you smoke and follow his or her advice about these other medicines.

✓ How and when to use this medicine

Check the foil is not broken before use. If it is, do not use that cartridge.

When to use the inhalator

Read all of the following information carefully before using the inhalator:

- Follow the instructions in the table on the back of the leaflet. The table shows when you should use the inhalator and the maximum amount of inhalator cartridges you should be using each day
- See the “How to use the inhalator” instructions to make sure that you use the inhalator correctly to ensure that nicotine is released and passes into your body through the lining of your mouth

The number of inhalator cartridges you use each day will depend on how many cigarettes you smoke and how strong they are.

- Boots NicAssist 15 mg Inhalator should be used **whenever** the urge to smoke is felt or when you would **normally expect** to have cravings to smoke
- It is recommended that to successfully reduce the amount of cigarettes you smoke or stop smoking completely you should use the inhalator as much as possible and it is up to you how many inhalations (puffs) you take, how often you take them and for how long
- **If you are ready to stop smoking completely**, you should use the inhalator, when needed, to replace all of your cigarettes. As soon as you feel ready (this could be after a number of weeks or months) you should reduce the number of cartridges used per day until you no longer need to use the inhalator
- **If you are not yet ready to stop smoking completely**, you should replace as many

cigarettes as possible with the inhalator. Boots NicAssist 15 mg Inhalator provides a safer alternative to smoking for you and those around you, as it is the toxins in cigarette smoke that cause harm, not the nicotine. Reducing the amount of cigarettes you smoke may also help you to become more motivated to stop smoking. As soon as you feel ready, you should aim to stop smoking completely

- **You can also use the inhalator when you can't or don't want to smoke**, such as social occasions e.g. at a party, in the pub, or for when you are at work, or on a plane or train etc.

When making an attempt to stop smoking completely behavioural therapy, advice and support will normally improve the success rate.

Adults and children of 12 years and over

Age	How often to use
Adults and children of 12 years and over	Use the inhalator when required , up to a maximum of 6 cartridges per day
Don't use more than 6 cartridges per day.	

You should always aim to stop smoking completely whilst using the inhalator.

If you are unable to reduce your use of the inhalator you should ask for help and advice from a pharmacist, nurse or doctor.

Do not give this medicine to children under 12 years of age.

How to use the inhalator

See the directions below.

Setting up the inhalator

1. Take the sealed plastic tray from the box. Peel back the foil.
2. Take the plastic mouthpiece from the tray.
3. Twist the two sections of the mouthpiece until the two marks line up. Then pull the mouthpiece apart.
<<Pictogram of how setting up the inhalator>>
4. Take a cartridge from the tray. Push the cartridge firmly into the bottom of the mouthpiece until the seal breaks.
5. Put the top section on the mouthpiece, lining up the two marks. Push together firmly to break the cartridge seal.
6. Twist to lock.

Special information about using the inhalator

Using the inhalator

1. To use the inhalator, take either deep or shallow puffs. Choose the way that suits you. Either way, your body will receive the amount of nicotine required to relieve and/or prevent cravings.

You may find it takes more effort than inhaling from a cigarette, but the amount of nicotine you get through the lining of your mouth is the same whether you take deep or shallow puffs

2. The amount of nicotine that you may get from one puff from the inhalator is less than that you may get from a cigarette and you may need to take more puffs from the inhalator.

It is up to you how many inhalations (puffs) you take, how often you take them and for how long.

3. Each cartridge will provide you with about 40 minutes worth of puffs. You can divide this time how you like. For example, you could use a cartridge for four 10 minute inhalation periods. Or you could use a cartridge for 10 minutes on waking and then for six periods of 5 minutes later on in the day.

Once the cartridge is used up, normally after a total of 40 minutes of intense use, you will need to change it.

Changing a cartridge

1. Open the mouthpiece as in step 3 of “Setting up the inhalator”. Pull out the cartridge and dispose of it safely (see “**How to clean, store and dispose of this medicine**”)
2. Put a new cartridge into the inhalator as in steps 4 to 6 of “Setting up the inhalator”.

Effect of temperature on the inhalator

The inhalator works best at room temperature and it is best not to use the inhalator in the cold.

In cold surroundings (below 15°C or 59°F) you may have to inhale more often to get the same amount of nicotine as when using the inhalator at room temperature.

When you are in surroundings above 30°C or 86°F, you should inhale less often to avoid taking in too much nicotine.

- ! If you have used the inhalator too often or too much:** You may get the following – nausea (feeling sick), vomiting, salivation, pain in your stomach, diarrhoea, sweating, headache, dizziness, hearing disturbance, weakness. **If this happens stop using the inhalator and do not smoke. Contact a doctor or hospital casualty department straight away.** Take the medicine and this leaflet with you.

If a child under 12 accidentally uses, swallows, sucks or chews 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 inhalator such as rash, itching or swelling of the tongue, mouth or throat (go straight to casualty if severe)
- you experience seizures (fits)

Effects related to stopping smoking (nicotine withdrawal)

You may experience unwanted effects because by stopping smoking or using the inhalator when you are unable to smoke you have reduced the amount of nicotine you are taking. You may also experience these effects if you use too few inhalator cartridges or puffs from the inhalator 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
- Dizziness, lightheadedness, blurry vision, nausea
- Cough
- Constipation
- Bleeding gums
- Mouth ulcers
- Swelling of the nasal passages and back of the throat

Effects of too much nicotine

It is possible to inhale too much nicotine if you use the inhalator in very warm surroundings

(see “**Effect of temperature on the inhalator**”). You may also get these effects if you are not used to inhaling tobacco as you smoke. You may be able to relieve these effects by using the inhalator less often.

These effects include:

- Feeling faint, feeling sick (nausea), headache

Side effects of the inhalator

When you first start using the inhalator you may be more likely to notice some of these side effects.

Very common side effects:

(more than 1 in every 10 people are affected)

- Headache, throat irritation
- Feeling sick, hiccups, inflammation of the mouth

Common side effects:

(less than 1 in every 10 people are affected)

- Allergic reactions
- Burning sensation in the mouth, dizziness, taste changes, pins and needles
- Cough
- Stomach pain, heartburn, diarrhoea, wind
- Dry mouth, being sick, increase in saliva
- Feeling tired, nasal congestion

Uncommon side effects:

(less than 1 in every 100 people are affected)

- Abnormal dreams
- Changes in heart rhythm (you may notice a fast heart rate or beat)
- Flushing, high blood pressure
- Throat tightness, difficulty breathing, shortness of breath, hoarseness of the voice, sneezing
- Belching, inflammation of the tongue, mouth ulcers, tingling mouth
- Itching, skin rash, hives, excess sweating
- Jaw pain
- Generally feeling unwell or weak, chest pains

Rare side effects:

(less than 1 in every 1,000 people are affected)

- Difficulty swallowing, retching, mouth feeling numb

Very rare side effects:

(less than 1 in 10,000 people are affected)

- Abnormal beating of the heart

Side effects with an unknown frequency:

- Severe allergic reaction, swelling or redness of the skin
- Blurred vision, watery eyes
- Dry throat, stomach discomfort, lip pain

- Tightness of the jaw

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

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed on this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

How to clean, store and dispose of this medicine

Cleaning the inhalator

Clean the empty mouthpiece several times a week by rinsing it in water.

Storing the inhalator and cartridges

Store below 25°C.

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 children.

Dispose of any cartridge that has been inserted into the mouthpiece within 48 hours, even if it has not been used.

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

Dispose of any used inhaler cartridges safely.

When a cartridge is used up, it is very important that you dispose of the empty cartridge carefully as it still contains some nicotine fixed to the plug. This nicotine is not available for inhalation but could be harmful to children or pets if swallowed or sucked.

You can return the empty cartridge to the foil tray then dispose of all the empty cartridges with your household rubbish.

What is in this medicine

Each inhalation cartridge contains Nicotine 15 mg, which is the active ingredient.

As well as the active ingredient, the inhalation cartridges also contain menthol.

Boots NicAssist 15 mg Inhalator consists of a plastic mouthpiece into which you insert a tube-like cartridge containing 15 mg of nicotine, the active ingredient, held in a porous plug.

The plug also contains menthol to give the nicotine a slight minty flavour.

Boots NicAssist 15 mg Inhalator is supplied as either a starter or a refill pack.

The starter pack contains a plastic tray sealed with foil containing 4 cartridges and a plastic mouthpiece.

The refill pack contains a mouthpiece and 20 cartridges.

Not all pack sizes may be marketed.

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 Limited 50 -100 Holmers Farm Way, High Wycombe, Buckinghamshire, HP12 4EG, UK..

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If you would like any further information about this product, please contact The Boots

Company PLC Nottingham NG2 3AA.

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