



PACKAGING SPECIFICATION

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nicorette®

**1.5mg inhalator
nicotine
inhalation cartridges**

**What should you know about
nicorette® 1.5mg inhalator
(nicotine 15 mg per cartridge)**

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® inhalator is a nicotine replacement therapy (NRT). It is used to relieve and/or prevent withdrawal symptoms and reduce the cravings you get when you try to stop smoking or when cutting down the number of cigarettes you smoke.

Ideally you should always aim to stop smoking. You can use NICORETTE® inhalator to achieve this by using it to completely replace all your cigarettes.

However NICORETTE® inhalator can also be used in other ways,

- if you feel unable to stop smoking completely, or wish to replace certain cigarettes and therefore it can help you to cut down the number of cigarettes you smoke,
- at those times when you can't or do not want to smoke. For example,
 - Where you don't want to smoke and avoid harm to others e.g children or family.
 - Smoke free areas e.g Pub, work, public transport e.g aeroplanes.

It may also help increase your motivation to quit. When making a quit attempt a behavioural support programme will increase your chances of success. Details of NICORETTE® ActiveStop are at the end of this leaflet.

What does nicorette® inhalator do?

When you stop smoking or cut down the number of cigarettes you smoke, 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 use NICORETTE® inhalator, air is drawn through the inhalator and nicotine is released. The nicotine is absorbed into your body through the lining of your mouth. This relieves the unpleasant 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.

Benefits you can get from using NRT instead of smoking

For the best effect, ensure that you use nicorette inhalator correctly – see "How to Use NICORETTE® inhalator".

The benefits of stopping smoking clearly 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 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.

2 Before using this medicine

⚠ Do not use nicorette® inhalator:

- if you have an allergy to nicotine or any of the other ingredients.
- If you are a child under 12 years of age.

⚠ 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, 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 a long term throat disease or difficulty breathing due to bronchitis, emphysema or asthma. NICORETTE® inhalator may not be suitable for you to use and you may be advised to use a different type of NRT.
- 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 – monitor your blood sugar levels more often when starting to use nicorette inhalator as you may find your insulin or medication requirements alter.
- if you are taking any 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.

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 reach and sight of children.

⚠ If you are pregnant or breast-feeding

If you are pregnant:

- 1) Firstly, you should try to give up smoking without NRT. Stopping completely is by far the best option. The earlier and quicker you do this the better it is for you and your baby.
- 2) Secondly, if you can't manage this, you can use NRT as a safer alternative to smoking 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® inhalator 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:

- 1) Firstly, you should try to give up smoking without NRT.

- 2) Secondly, 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® inhalator to ensure 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® inhalator

Follow the instructions 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 box.
- 3 Twist the two sections of the mouthpiece until the two marks line up. Then pull the mouthpiece apart.
- 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.



① Special information about using the inhalator

Using the inhalator

1 Inhale using the inhalator, either deeply or shallow puffs. Choose the way that suits you. Either way, your body will receive the amount of nicotine required to give craving relief.

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

- 2 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 of intense use. 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 five minutes later on in the day. Once the cartridge is used up, 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.

2 Put a new cartridge into the inhalator as in steps 4-6 of *Setting up the inhalator*.

Dosage and temperature

NICORETTE® 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.

When to use the inhalator

If you are able to stop smoking you should use the inhalator, when needed, in place of cigarettes. As soon as you can (this could be after a number of weeks or months) you should reduce the number of cartridges until you have stopped using them completely.

If you are unable to stop smoking or do not feel ready to quit at this time, you should replace as many cigarettes as possible with the inhalator. There are toxins in cigarettes that can cause harm to your body. NICORETTE® inhalator provides a safer alternative to smoking, for both you and those around you. Reducing the amount of cigarettes may also help you to become more motivated to stop smoking. As soon as you are ready you should aim to stop smoking completely.

You can also use the inhalator on those occasions when you can't or don't want to smoke e.g. Social situations such as a party, in the pub or when at work.

When making a quit attempt behavioural therapy, advice and support will normally improve the success rate. If you have quit smoking and want to stop using the inhalator but are finding this difficult you should contact your doctor, nurse or pharmacist for advice.

Below is the dosage information for nicorette inhalator.

Age	Dose
Adults and children aged 12 years and over	As needed up to a maximum of 6 cartridges per day

- Do not use more than 6 cartridges per day.
- The frequency with which you use the cartridges and the length of time it lasts will depend on how many cigarettes you smoked and how strong they were.

If you have used nicorette® inhalator too much

If you have used more than the recommended number of cartridges, you may experience nausea (feeling sick), 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 uses an inhalator or swallows a cartridge

- Contact a doctor or your nearest hospital Accident and Emergency department immediately if a child under 12 years uses your inhalator, or chews, sucks or swallows a cartridge. 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® inhalator 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® inhalator cartridges 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

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

Very common side-effects

(more than 1 in every 10 people are affected)

- headache
- cough
- irritation of the mouth or throat

Common side-effects:

(less than 1 in every 10 people are affected)

- dizziness
- nasal congestion
- stomach discomfort
- hiccups
- 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. Also you can help to make sure medicines remain as safe as possible by reporting any unwanted side-effects via the internet at www.mhra.gov.uk/yellowcard; alternatively you can call Freephone 0800 100 3352 (available between 10am – 2pm Monday to Friday) or fill in the paper form available from your local pharmacy.
- When you stop smoking you may also develop mouth ulcers. The reason why this happens is unknown.

5 Cleaning, storing and disposal

Cleaning the inhalator

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

Storing the inhalator and cartridges

- Keep NICORETTE® inhalator 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.

- Do not store above 25°C.
- Do not use NICORETTE® inhalator after the 'Use before' date shown on the carton.
- Dispose of any cartridge that has been inserted into the mouthpiece within 48 hours even if it has not been used.

Disposal

Dispose of your used inhalator 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.

6 Further information

What's in this medicine?

The active ingredient is Nicotine.

Other ingredients are: Menthol.

What the medicine looks like

NICORETTE® 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.

Pack sizes: 4, 20 or 36

Each pack contains a plastic tray sealed with foil containing 4, 20 or 36 cartridges and a plastic mouthpiece.

Not all pack sizes may be marketed.

Who makes nicorette® inhalator?

The Product Licence holder is McNeil Products Ltd, Maidenhead, Berkshire, SL6 3UG, UK.

The manufacturer is McNeil AB, Helsingborg, Sweden.

This leaflet was prepared in August 2012. ©

Information about nicorette® ActiveStop

NICORETTE® ActiveStop 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.

Call 0800 244 838

for information.

