

NicAssist 10 mg inhalator (Nicotine)

This leaflet provides a summary of the information you should know before using this medicine. Please read it carefully. If you want to know more about your condition or this medicine, your pharmacist can help.

The name of your medicine is Boots NicAssist 10 mg inhalator.

What is in this medicine

This medicine is available as a starter pack or a refill pack. The starter pack contains a mouth piece, 6 cartridges and an empty child proof box to carry these items in. The refill pack contains a spare mouthpiece and 42 cartridges.

Each cartridge contains a porous plug containing nicotine $10\ mg$ which is the active ingredient.

As well as the active ingredient these cartridges also contain menthol which provides a slight mint flavour.

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What this medicine is for

This product belongs to a group of medicines called nicotine replacement therapy.

It can be used to relieve the cravings for nicotine which people get when they try to stop smoking.

When you stop smoking, your body misses the nicotine which you have been absorbing from the smoke. Unpleasant feelings and a desire to smoke ('craving') show that you were dependent on the nicotine. You may also miss the frequent movements with your hand to the mouth, inhaling etc, which are known as habitual movements.

When you draw air through the inhalator, nicotine is carried into the mouth, where it passes into the body through the mouth lining. This nicotine relieves the craving and by your gradual reduction in use of the inhalator also tackles the dependence. As you decrease the use of the inhalator so dependence and habitual movements are tailed off together. Remember, the inhalator provides only nicotine. The dangerous tars and carbon monoxide in cigarette smoke are avoided. Your chances of giving up smoking are greater if you get encouragement from family, friends, your doctor or pharmacist.

Before you use this medicine

This medicine can be used by adults over the age of 18 years. However, some people should not use this medicine or should seek the advice of their pharmacist or doctor first.

Do not use if:

- · You are pregnant or breastfeeding
- You are under 18 years
- · You are allergic to nicotine or menthol
- · You are a non-smoker
- You are taking or smoking any nicotine or tobacco products during the NicAssist inhalator course

Talk to your pharmacist or doctor if:

- You suffer from angina, high blood pressure, severe heart problems or circulatory problems
- You have, or have had, a stomach ulcer or other stomach problems
- You have persistent indigestion or pains in the chest
- You have had a recent heart attack
- You have liver or kidney problems

 You are diabetic, or suffer from an overactive thyroid, or high blood pressure due to a tumour near your kidney (a condition known as phaeochromocytoma)

Other important information

This medicine is best used at room temperature. Low temperatures may delay the release of nicotine and high temperatures increase the amount of nicotine released. If you are in a place where the temperature is over 30°C do not use the inhalator or take fewer inhalations than usual. If you have difficulty in breathing due to asthma, bronchitis or other respiratory conditions the inhalator may not be suitable for you. Ask your pharmacist about other forms of nicotine replacement treatment available e.g. gum, patches.

Boots NicAssist inhalator and 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 including the following:-

- Theophylline (for breathing problems)
- Imipramine, olanzapine, clozapine, clomipramine, tacrine, fluvoxamine (for depression and other mental problems)
- Pentazocine (for pain), flecainide (for heart problems)

If you are unsure about interactions with any other medicines, talk to your pharmacist.

How to use this medicine

NicAssist inhalator can be used whenever the urge to smoke comes on. You can use up to a maximum of 12 cartridges a day. For most people between 6 and 12 cartridges a day are effective. The number of cartridges you use should be gradually reduced over a 3 month period.

1. Over a period of up to 8 weeks whenever the craving to smoke comes on, use the inhalator instead of smoking (do not smoke, use more than 12 cartridges a day, or use other nicotine containing products as well)

- 2. Over the next two weeks cut the number of cartridges you use each day by half
- 3. Over the next 2 weeks reduce the number to none at all
- 4. If you go back to smoking, discuss this with your doctor or pharmacist for further help

Do not use if you are under 18 years.

Do not take more than the dose recommended above.

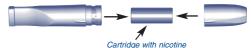
What to do in case of overdose: If you use too many cartridges, or a child uses your inhalator, talk to a doctor or hospital casualty department straight away. Take your medicine with you.

Directions for using the inhalator

- I. Take a tray from the box and peel back the foil
- 2. Remove a cartridge from the plastic tray
- Separate the mouthpiece by twisting the two halves until the two marks line up. The mouth piece can now

be pulled apart

4. Take a cartridge and push it firmly into the bottom of the mouth piece until the seal breaks



- 5. Put the top on the mouthpiece, line up the marks and push the top and bottom together firmly to break the top seal of the cartridge
- 6. Twist to lock
- 7. The inhalator is now assembled and can be used
- 8. When a cartridge is empty, open the mouth piece as in (3) above, pull out the used cartridge and dispose of it carefully
- 9. Follow steps above to replace the cartridge

Inhaling from the inhalator

You can either get nicotine by inhaling deeply or by

shallow puffing. The amount of nicotine you absorb through the lining of your mouth is the same, which ever method of inhalation you choose. You may find the effort required is greater than inhaling on a cigarette. It is up to you how many inhalations (puffs) you take, how often you take them and for how long. You can also choose what method to use. The amount you need will depend on the amount of nicotine you have been used to.

Each cartridge will provide you with about 20 minutes use. You can divide this time how you like. For example, you could use one cartridge twice, each time for 10 minutes. Perhaps another way would be to use one cartridge for 10 minutes on waking up and then for two periods of five minutes later on.

How many cartridges you use during a day will depend on how many cigarettes you smoked and how strong they were. Try not to use too many or too few cartridges but use the inhalator as needed to relieve your withdrawal symptoms and cravings to smoke. For a person smoking around 20 cigarettes a day we would recommend they use between 6 and 12 cartridges a day.

You should not use more than 12 cartridges a day. One puff from a cigarette is equivalent to 10 puffs on the inhalator. One cartridge is roughly equivalent to 2 to 3 normal strength cigarettes.

The inhalator works best at room temperature. In cold surroundings (below 15°C or 59°F) you will have to inhale more often to get the same amount of nicotine as when using the inhalator at room temperature. It is best not to use the inhalator in the cold. When you are in surroundings above 30°C or 86°F, you should inhale less often, to avoid taking in too much nicotine.

Disposal of used cartridges

It is very important that after you have used a cartridge, you should dispose of it safely. The cartridge will still

contain some nicotine but this remains fixed to the plug so it is not available for inhalation.

However, the nicotine that remains in the cartridge could still harm children or pets if the cartridge is swallowed. We recommend that you return the cartridges to the foil tray and then dispose of them with your household rubbish.

You should clean the empty mouthpiece several times a week by rinsing it in water and storing it in the plastic case.

Your craving for nicotine

Nicotine from the inhalator gets into the blood within a few minutes of starting it. The levels build up as you use it, relieving your craving. If you use the inhalator intensively the highest level of nicotine in the blood is reached after about 20 minutes.

Craving for nicotine may never completely go and some people who have given up

After you take this medicine

Most people can use this medicine without any problems but sometimes you may notice some side effects which may include:

- Hiccups, irritable or sore throat, mouth ulcers, mouth discomfort, sore gums, a dry mouth or thirst
- Headache, nasal congestion, runny nose or sinusitis, chest pain, breathlessness, cough
- · Indigestion, heartburn, nausea, vomiting, diarrhoea, wind
- · Anxiety, depression, bone pain, pins and needles
- Allergy

Many of these effects resemble those seen when you smoke too much and may be due to over-use of the inhalator in

relation to the amount you used to smoke. These effects may also occur if you continue to smoke whilst using the inhalator.

You may take in too much nicotine if you use the inhalator in very warm surroundings.

Under use of the inhalator may cause signs of nicotine withdrawal such as dizziness, headache or sleeplessness.

Rarely, users may transfer their dependence on cigarettes to dependence on the inhalator.

If concerned, or if anything else unusual happens, talk to a pharmacist or doctor.

How to store this medicine

Do not store above 30°C.

Keep this medicine in a safe place away from the sight and reach of children, preferably in a locked cupboard. Leaflet prepared February 2004

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