

NICORETTE® Inhalator - Nicotine Replacement Therapy (NRT)

Consumer Medicine Information

What is NICORETTE®?

NICORETTE® is a range of NRT medicines intended to support you while you give up smoking by relieving withdrawal symptoms and reduce cravings for nicotine which people get when they first stop smoking or cut down the number of cigarettes they smoke while trying to stop smoking.

NICORETTE® products are available in a variety of forms so that you can choose the NRT that suits you most.

NICORETTE® Inhalator 15 mg is available in a 4 cartridge plus mouthpiece pack and a 20 cartridge plus 2 mouthpieces pack.

The NICORETTE® product range includes Gum (flavoured and unflavoured), Microtab (a tiny tablet that dissolves slowly under the tongue) and Patch (to apply to the skin).

How does NICORETTE® Inhalator work?

NICORETTE® Inhalator releases nicotine into your mouth when you draw air in through the inhalator. The nicotine is absorbed through the lining of your mouth and enters your bloodstream.

This nicotine is sufficient to relieve unpleasant withdrawal symptoms and to decrease the cravings for smoking.

NICORETTE® Inhalator helps you give up smoking by relieving nicotine cravings. It will not give you the "buzz" or "hit" you get from a cigarette.

What is in NICORETTE® Inhalator?

NICORETTE® Inhalator consists of a plastic mouth piece and cartridge that must be put together as described on the side of the pack before use. The mouthpiece should be rinsed with water several times a week.

Each inhalator cartridge contains 15 mg nicotine.

It also contains menthol as a flavour.

It does not contain sugar (sucrose) or animal products.

How do I assemble the NICORETTE® Inhalator?

1. Assemble inhalator just before use. Opened cartridges should not be used the next day.
2. Align marks on the mouthpieces. Pull off the top.
3. Release one cartridge from the blister tray. Press the cartridge firmly into the bottom of the mouthpiece until the seal breaks.
4. Replace the top on them mouthpiece. Align the marks on the mouthpiece and push the top and bottom firmly together to break the seal of the cartridge. Twist to misalign the marks and lock the mouthpiece.
5. Inhalator is now ready for use.

When should I NOT use NICORETTE® Inhalator?

Do not use NICORETTE® Inhalator if you are allergic to nicotine or menthol or after the 'Use before' date on the box or blister strip.

I have problems with my heart and/or circulation. Should I be using NICORETTE® Inhalator?

For heart conditions not requiring you to be in hospital, using NRT is better than continuing to smoke.

Talk to your doctor before use if:

- You have heart disease such as palpitations (fast or irregular heart beats) or angina.
- You have heart disease (including heart attack and disorders of the heart rate/rhythm) or a stroke for which you are in hospital.
- You have other heart disease or circulation problems.

What if I have diabetes?

If you have diabetes that is controlled with insulin you should monitor your blood sugar levels more often when starting to use NICORETTE® Inhalator as you may find your insulin/medication requirement changes.

What if I have a sore mouth or throat or get a sore mouth or throat while using NICORETTE® Inhalator?

If your mouth or throat is red/inflamed or becomes red/inflamed you should talk to your doctor/pharmacist before use. If your mouth or throat is sore because of a cold or flu it may not be necessary to stop therapy with NICORETTE® Inhalator.

Which medicines should I be careful about taking while using NICORETTE® Inhalator?

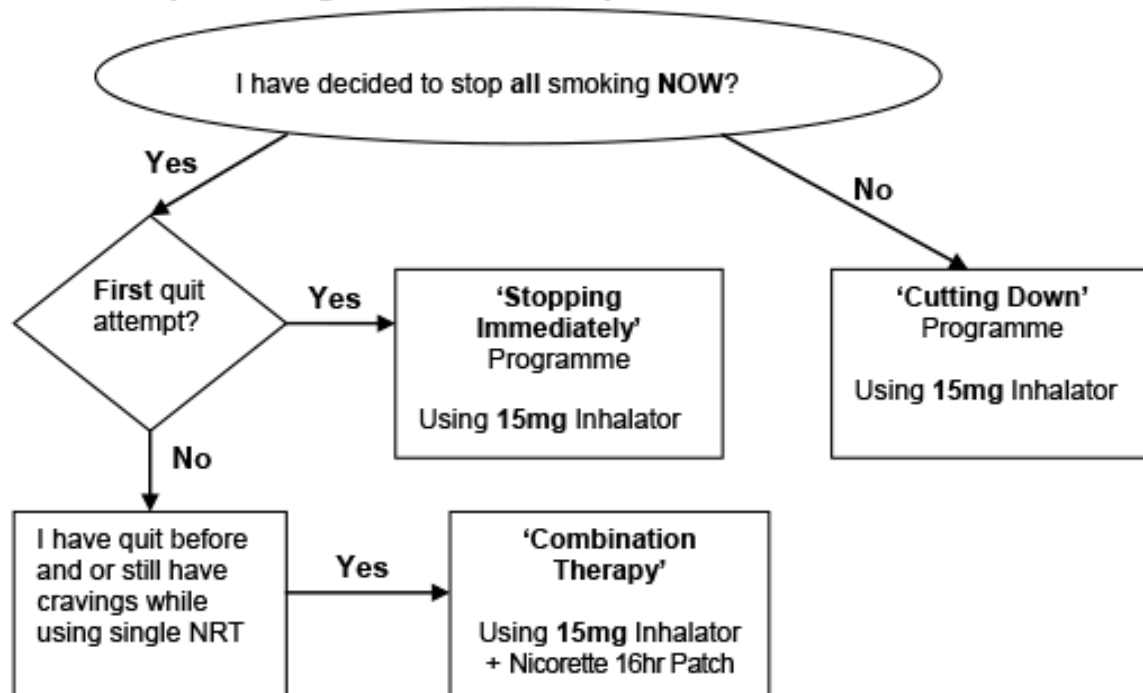
Some medicines may require a change in dosage when you stop smoking or cut down smoking. These include: Theophylline (used for asthma); Imipramine, Clomipramine and Fluvoxamine, (used for depression); Pentazocine, (used for pain relief), Clozapine, Olanzapine and Tacrine, (used for mental conditions); Flecainide, (used for irregular and/or rapid heartbeat); caffeine.

If you are taking any other medicines, including medicines that you buy without a Prescription you should talk to your doctor/pharmacist.

What if I am Pregnant?

Smoking during pregnancy is associated with risks such as poor growth of the baby before birth, premature birth or stillbirth. Stopping smoking is the single most effective intervention for improving both your health and that of your baby and the earlier smoking stops the better.

There are 3 stop smoking methods on the pack, which one is recommended for me?



Ideally, stopping smoking during pregnancy should be achieved without NRT. However if you have tried and this is not possible, NRT may be recommended. Products that are used intermittently (i.e. Gums, Inhalators & Microtabs) are preferable to nicotine patches. However, patches may be preferred if you have nausea or sickness. Patches, if used, should be removed before going to bed at night.

What if I am Breast feeding?

Tobacco smoke produces breathing and other problems in babies and children. If you need to use NRT to help you quit, you should use NRT products that are taken intermittently (i.e. Gums, Inhalators & Microtabs, NOT Patches). Try to breast-feed at a time just before you use the product to ensure that the baby gets the smallest amount of nicotine possible.

Can I eat or drink while using NICORETTE® Inhalator?

You should not use NICORETTE® Inhalator while eating or drinking as this may cause excessive swallowing of nicotine, reducing the effectiveness of the Inhalator. Do not drink acidic beverages, such as coffee or soft drinks, for 15 minutes before using as they can interfere with the absorption of nicotine.

See pack for directions for adults for "Stopping immediately" and "Cutting down" Programmes.

ADOLESCENTS (12 YEARS AND OVER) Use in adolescents under doctor/pharmacist supervision only

If I am under 18 years of age how often do I use the inhalator?

NICORETTE® Inhalator should only be used as your doctor/pharmacist tells you to. The recommended length of treatment is 12 weeks.

Do not use more than for more than 12 weeks unless your doctor/pharmacist has told you to. **Do not give to children under 12 years.**

What if I use NICORETTE® Inhalator too much?

If you have used more than the recommended number of cartridges with NICORETTE® Inhalator you may experience nausea, salivation, pain in your abdomen, sweating, diarrhoea, headache, dizziness, hearing disturbance or weakness. If any unwanted effects occur, contact a doctor or your nearest hospital Accident and Emergency department immediately. If you go to the doctor or hospital, take this leaflet and the pack with you.

What should I do if a child has used, sucked or swallowed a NICORETTE® Inhalator or cartridge?

Young children can be poisoned by small amounts of nicotine. If a child under 12 years chews, sucks or swallows a NICORETTE® Inhalator or cartridge contact a doctor or your nearest hospital Accident and Emergency department immediately, telephone your doctor or Poisons Information Centre for advice (telephone 13 11 26 (AU); 0800 764 766 (NZ)), or go to Accident and Emergency at your nearest hospital.

If you take the child to the doctor or hospital, take this leaflet and the pack with you.

Are there any unwanted side effects from NICORETTE® Inhalator?

Like all medicines, NICORETTE® Inhalator can have side-effects. These effects are rarely serious. As many of the effects are due to nicotine, they can also occur when nicotine is obtained by smoking.

Some unwanted effects you may notice when you start to use NICORETTE® Inhalator for the first time include hiccups, sore throat, increased saliva in your mouth, mild indigestion or heartburn.

Other commonly reported side-effects include dizziness, vomiting, or sore mouth.

Uncommonly reported side-effects include chest palpitations, redness or itching of the skin.

Very rarely, abnormal beating of the heart has been reported.

You may experience some unwanted effects because by stopping smoking you have reduced the amount of nicotine you are taking. These effects are nicotine withdrawal symptoms and include irritability/aggression, feeling low, anxiety, restlessness, poor concentration, increased appetite/weight gain, urges to smoke ("craving"), night-time awakenings/sleep disturbance and lowering of your heart rate. You may experience nicotine withdrawal symptoms if you use too few NICORETTE® Inhalator cartridges before you are ready to reduce your nicotine intake.

When you stop smoking, you may experience mouth ulcers.

If you notice these or any other unwanted effects not listed in this leaflet you should tell your doctor, nurse or pharmacist.

When should I see my doctor while using NICORETTE® Inhalator?

If you get chest pain, bad indigestion, an irregular (uneven) heart beat or develop an allergic reaction (swelling of the mouth and tongue, itching of the skin, ulceration and inflammation of the lining of the mouth), do not smoke or use NICORETTE® Inhalator or other nicotine medicines and see your doctor as soon as possible.

How do I combine use of NICORETTE® 15 mg Inhalator and Patch ('Combination Therapy')?

NICORETTE® Combination Therapy is more effective than using either product alone in people who have been unable to quit smoking using a single NRT product.

NICORETTE® 15 mg Inhalator in combination with NICORETTE® Patch

Each morning apply a NICORETTE® 15 mg/16 hour Patch to an intact area of skin. The NICORETTE® Patch should be removed before going to bed. After applying the NICORETTE® Patch use NICORETTE® 15 mg Inhalator whenever a craving occurs.

For best results, it is recommended that 2-3 inhalator cartridges are used per day. The maximum number of inhalator cartridges that can be used in conjunction with Patch is 6.

The combination of NICORETTE® 15 mg Inhalator and NICORETTE® Patch should be used in this way for 12 weeks. After this time you should wean yourself off NRT by either:

1. Using the NICORETTE® 10 mg/16 hour Patch for 2 weeks followed by the NICORETTE® 5 mg/16 hour Patch for 2 weeks while using the same number of inhalator cartridges that have been routinely used. Then when a patch is no longer needed, gradually reduce the number of inhalator cartridges until you no longer need them; OR
2. Stopping use of the NICORETTE® 15 mg/16 hour Patch and then gradually reducing the number of inhalator cartridges you use until you no longer need them.

How do I go about starting giving up?

You will need to plan your stop-smoking programme. Think about the times you will miss smoking the most and plan how you will cope on these occasions. Changing your routine may help you break the habit of smoking.

You will also need the support of others, your family, your friends, your pharmacist, family doctor or practice nurse or any one of a number of "quit smoking" organisations. **Do not be afraid to seek support or advice.**

Choose a day that you will start your **Stopping Immediately Programme** or **Cutting Down Then Stop Programme** so that you can plan to be ready. This allows you to:

- Pick the right day - set a date that is likely to be stress free.
- Tell friends, family and work colleagues that you are stopping smoking and that you envisage a tough time ahead. This will encourage them to support you.
- Make cigarette-free zones, eg the home, the car.
- Quit with a friend- you can help each other stick to your plan.
- Remove temptations.
- Take one day at a time, just promise yourself "I won't have a cigarette today" - every day that you have cut down or gone without a cigarette makes you a winner.
- Keep yourself busy - do something you enjoy.
- Think cash, not ash - your money will no longer be going up in smoke.
- Avoid putting on weight - start a gentle exercise regimen.
- If at first you don't succeed don't give up. Successful quitters keep trying.

What if I am having difficulties stopping smoking?

If you find it difficult to cut down and stop using NICORETTE® Inhalator, or are worried that without it you will start smoking again, talk to your healthcare professional.

For further information call our toll free info lines or visit our websites:

- **AUS:** 1800 029 979
www.nicorette.com.au
- **NZ:** 0800 446 147
www.nicorette.co.nz

Alternatively you can contact Quitline in Australia (Tel: 131 848/www.quitnow.info.au) for information, support and advice.

Remember, NICORETTE® products are not intended as a substitute for smoking, it is an aid to giving up.

Johnson & Johnson Pacific

- Australia
- Fiji

- New Zealand

45 Jones Street, Ultimo NSW 2007,
AUSTRALIA

And

Auckland, NEW ZEALAND

® Registered Trademark