

23 April 2012

NICORETTE® QuickMist - Nicotine Replacement Therapy (NRT)

What is NICORETTE®?

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

NICORETTE® comes in a variety of formats/products so that you can choose the format that suits you most.

NICORETTE® QuickMist is a mouth spray and is available in a 1mg nicotine/spray dose strength (mint flavour)

NICORETTE® is also available as a Gum, Microtab (a tiny tablet that dissolves slowly under the tongue), Lozenges, Inhalator and Patch (to apply to the skin)

Nicotine from NICORETTE® products is sufficient to relieve unpleasant withdrawal symptoms and to decrease the cravings for smoking.

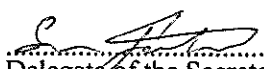
NICORETTE® QuickMist helps you give up smoking by relieving nicotine cravings. It will not give you the "buzz" or "hit" you get from a cigarette.

How does NICORETTE® QuickMist work?

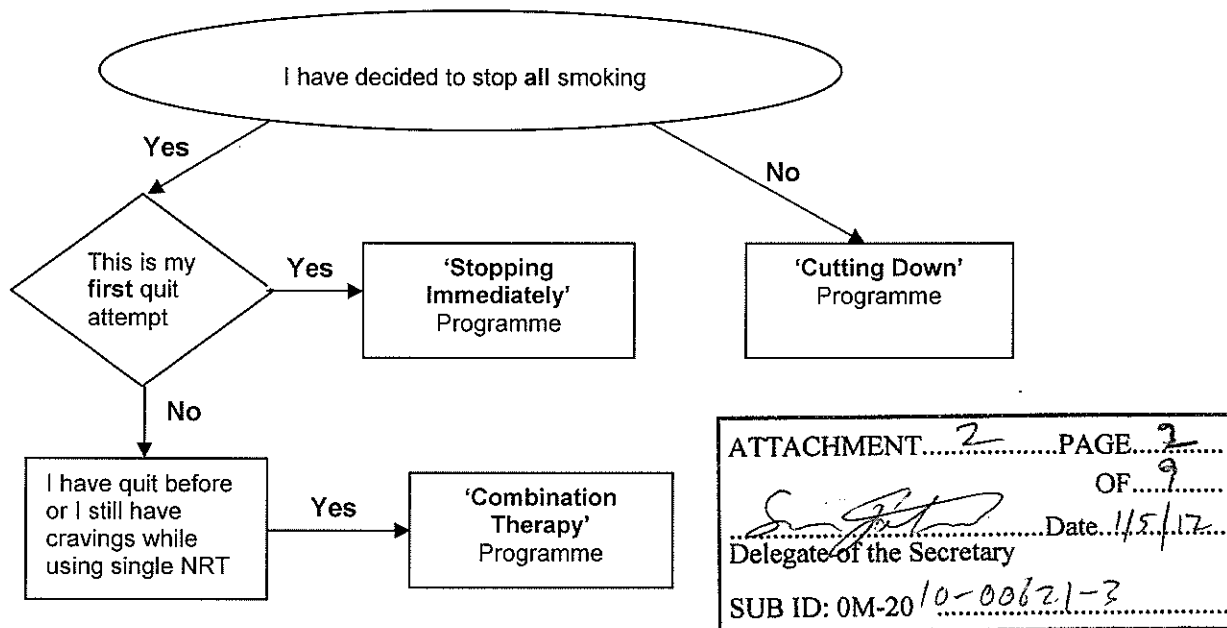
NICORETTE® QuickMist delivers nicotine into your mouth. The nicotine is absorbed through the lining of your mouth and enters your bloodstream. Any nicotine that is swallowed is broken down in your stomach and will not be effective. It is important NOT to swallow NICORETTE® QuickMist (as per instructions on the back of the pack) so that the nicotine is absorbed through the lining of the mouth.

What is in NICORETTE® QuickMist?

Each spray of NICORETTE® QuickMist contains 1 mg of nicotine, propylene glycol, anhydrous ethanol, trometamol, poloxamer 407, glycerol, sodium hydrogen carbonate, levomenthol, mint flavour, cooling flavour, sucralose, acesulfame potassium, hydrochloric acid and purified water.

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



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See pack for directions for adults for “Stopping immediately”, “Cutting down” and “Combination therapy”. See also “How do I combine use of NICORETTE® QuickMist and Patch?”

How do I use NICORETTE® QuickMist when stopping immediately?

Always use NICORETTE® QuickMist as stated in this package leaflet. You should check with your doctor or pharmacist if you are not sure.

The following table shows the recommended step by step process for NICORETTE® QuickMist.

For Adults 18 years and over

Step I: Weeks 1-6
Use 1 or 2 sprays when you would normally smoke a cigarette or have cravings to smoke. Use one spray first and if your cravings do not disappear within a few minutes use the second spray. If 2 sprays are required, future doses may be delivered as 2 consecutive sprays. For most smokers this means about 1 or 2 sprays every 30 minutes to 1 hour.
For example, if you smoke an average of 15 cigarettes per day, you should use 1 or 2 sprays at least 15 times during the day.
Do not use more than 2 sprays at a time, 4 sprays per hour for 16 hours or 64 sprays per day.

Step II: Weeks 7-9
Start reducing the number of sprays per day. By the end of week 9 you should be using HALF the average number of sprays per day that was used in Step I.

Step III: Weeks 10-12
Continue reducing the number of sprays per day so that no more than 4 sprays per day are used during week 12. Treatment should be stopped when the dose is reduced to 2-4 sprays per day.

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You may be tempted to smoke again after treatment has stopped. If you have a craving use one spray, or 2 sprays if one spray does not help within a few minutes.

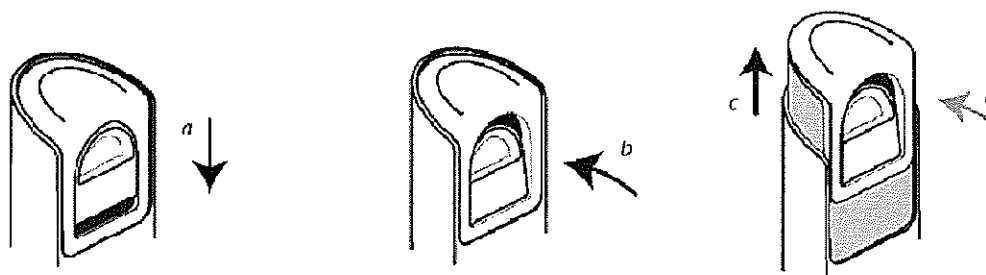
Normally you should use NICORETTE® QuickMist for 3 months, though no longer than 6 months. Consult your doctor or pharmacist if you need to use NICORETTE® QuickMist for longer than 6 months. Save any remaining doses of the spray, as craving for smoking may suddenly occur.

Do not exceed the maximum dose.

Do not give to children under 12 years.

Follow these instructions carefully and use the pictures to guide you

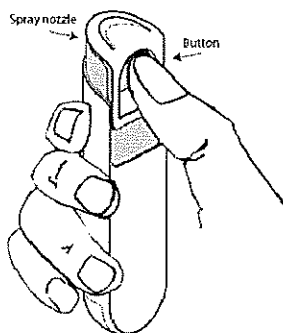
How to open the NICORETTE® QuickMist spray / To unlock nozzle

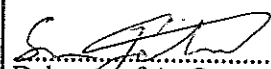


1. Use your thumb to slide down the button (a) until it can be pushed **lightly** inwards (b). Do not push too hard.
2. While pushing in, slide upwards (c) to unlock the top of the dispenser. Then release the button.

How to prime the NICORETTE® QuickMist spray

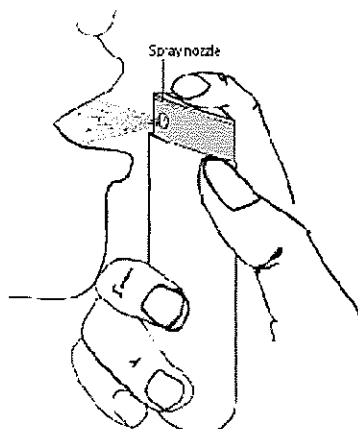
When you use the spray for the first time you must first load the spray pump. Point the spray nozzle safely away from you, any other adults, children or pets near you. Press the top of the NICORETTE® QuickMist with your index finger. Press several times until a fine spray appears. If you do not use the spray for 2 days, this loading procedure will need to be repeated.



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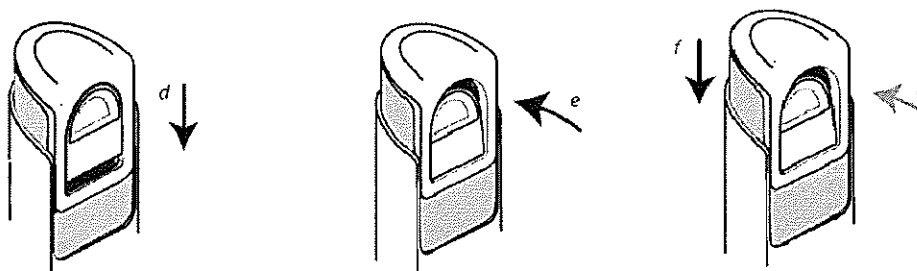
How to use the NICORETTE® QuickMist spray

3. Point the spray nozzle towards your open mouth and hold it as close to your mouth as possible.
4. Press the top of the NICORETTE® QuickMist to release one spray into your mouth, avoiding the lips. To avoid getting spray down your throat do not inhale while spraying. For best results, do not swallow for a few seconds after spraying.



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How to close the NICORETTE® QuickMist spray / To lock nozzle



5. Slide the button down (d) until it can be pushed inwards (e).
 6. While pushing in, slide the top of the dispenser downwards (f). Release the button. The NICORETTE® QuickMist spray is now closed.
- To take another dose repeat the steps above.

Close the NICORETTE® QuickMist spray every time after use to engage child resistant feature and prevent accidental spraying.

Take care not to spray the eyes while using the mouth spray. If you get spray in your eye, rinse thoroughly with water.

Do not eat or drink when administering the mouth spray.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

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

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® QuickMist whenever a craving occurs.

For best results, it is recommended that 1 dose of mouth spray is used when cigarettes would normally have been smoked. Do not use more than two sprays per hour for 16 hours or 32 sprays per day when you are using combination therapy with NICORETTE® Patch.

The combination of NICORETTE® QuickMist 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® 10mg/16 hour Patch for 2 weeks followed by NICORETTE® 5mg/16 hour Patch for 2 weeks while using the same number of sprays of NICORETTE®

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QuickMist in a day that you have routinely used. Then when a Patch is no longer needed, gradually reduce the number of sprays of mouth spray until you no longer need it. OR

2. Stop use of the NICORETTE® 15mg/16 hour Patch and then gradually reduce the number of sprays of NICORETTE® QuickMist that you use until you no longer need it.

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

How do I use NICORETTE® QuickMist for smoking reduction (reduce to stop, or cutting down programme)?

NICORETTE® QuickMist mouthspray should be used between smoking episodes to prolong the interval between cigarettes, with the aim of reducing smoking as much as possible. An attempt to stop smoking completely should be made when you feel ready, but no later than 6 months after starting to use NICORETTE® QuickMist mouth spray.

When you feel ready to stop smoking completely, follow the usage instructions shown above under the heading "How do I use NICORETTE® QuickMist when stopping immediately?"

See your doctor or pharmacist if you have not reduced the number of cigarettes you smoke after 6 weeks, or if you have not made an attempt at quitting completely within 9 months of starting the cutting down programme with NICORETTE® QuickMist.

ADOLESCENTS (12 YEARS AND OVER)

Use in adolescents under doctor/pharmacist supervision only

If I am under 18 years of age how should I use NICORETTE® QuickMist?

STOPPING IMMEDIATELY PROGRAMME	
During weeks 1-6	Use 1 or 2 sprays when you would normally have a cigarette or have cravings to smoke. Do not use more than 2 sprays at a time, 4 sprays per hour for 16 hours or 64 sprays per day.
During weeks 7-9	Start reducing the number of sprays per day. By the end of week 9 you should be using HALF the average number of sprays per day that was used in Step 1.
During weeks 10-12	Gradually reduce to 1-2 sprays per day and then stop use. Use beyond 12 weeks in adolescents is not recommended.

CUTTING DOWN PROGRAMME
The recommended duration of NRT treatment in adolescents is 12 weeks. You should seek advice from your doctor/pharmacist before attempting this programme.

Do not give to children under 12 years.

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When should I NOT use NICORETTE® QuickMist?

Do not use NICORETTE® QuickMist if you are allergic to nicotine or to any of the ingredients listed above or after the expiry date which is stated on the NICORETTE® QuickMist carton and on the blister card.

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

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 heartbeats) 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® QuickMist as you may find your insulin/medication requirement changes.

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

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 (used for mental conditions); Ropinirole (used for Parkinson's disease); caffeine.

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

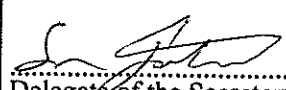
What if I am Pregnant?

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.

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, Lozenges & Mouth Sprays) 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, Lozenges & Mouth Spray NOT Patches) and 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.

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Can I eat or drink while using NICORETTE® QuickMist?

You should not use NICORETTE® QuickMist when eating or drinking as this may cause swallowing of nicotine, reducing the effectiveness of the mouth spray.

Do not drink acidic beverages, such as coffee or soft drinks, for 15 minutes before using NICORETTE® QuickMist, as they can interfere with the absorption of nicotine.

What if I use too much NICORETTE® QuickMist?

If you have used more than the recommended number of sprays of NICORETTE® QuickMist 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 or swallowed NICORETTE® QuickMist?

Young children can be poisoned by small amounts of nicotine. If a child under 12 years uses or swallows NICORETTE® QuickMist 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® QuickMist?

Like all medicines, NICORETTE® QuickMist 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 common unwanted effects you may notice when you start to use NICORETTE® QuickMist for the first time include headache, nausea, vomiting, tingling/burning sensations, inflammation or pain in your mouth or lips, changes in taste perception, changes in saliva production, dryness of the mouth, indigestion and hiccups. These effects may be due to incorrect use of NICORETTE® QuickMist like using too much, or swallowing too much nicotine.

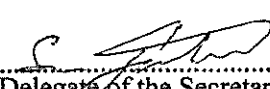
Other commonly reported side-effects include dizziness, chest palpitations and coughing.

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 under use NICORETTE® QuickMist 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.

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

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® QuickMist or other nicotine medicines and see your doctor as soon as possible.

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 **Stop Smoking 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® QuickMist, 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 access our websites:

AUS: 1800 029 979 www.nicorette.com.au

NZ: 0800 446 147 www.nicorette.co.nz

Alternatively, in Australia you can contact Quitline (Tel: 131848 / www.quitnow.info.au) or The Quit Group in New Zealand (Tel: 0800 778 778/www.quit.org.nz) for information, support and advice.

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

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Nicorette QuickMist Proposed Pack Insert (Marketed)

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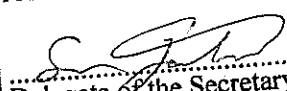
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