

nicorette®

QuickMist 1mg/spray mouthspray nicotine

What should you know about nicorette® QuickMist mouthspray (nicotine 1 mg per spray)

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.

nicorette®

QuickMist 1mg/spray mouthspray

PACKAGE LEAFLET:
INFORMATION FOR THE USER

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1 What this medicine is for
NICORETTE® QuickMist 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® mouthspray to achieve this by using it to completely replace all your cigarettes. However NICORETTE® mouthspray 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 and 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.

What does NICORETTE® QuickMist do?

When you stop smoking 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® QuickMist, nicotine passes rapidly 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.

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

Benefits you can get from using NRT instead of smoking

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

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 diseases 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.

2 Before using this medicine

Do not use nicorette® QuickMist:

- if you have an allergy to nicotine or any of the other ingredients.
- if you are 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, chest pain, disorders of heart rate or rhythm, angina, high blood pressure 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 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® QuickMist 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 may require the dose of these medicines to be adjusted.

► If any of these apply, talk to your doctor, nurse or pharmacist.

Important information about some of the ingredients

NICORETTE® QuickMist contains small amounts of ethanol (alcohol), less than 100 mg per spray. This medicine contains 11 mg propylene glycol in each spray which is equivalent to 150 mg/mL.

It also contains butylated hydroxytoluene (E 321) which may cause local skin reactions (e.g. contact dermatitis), or irritation to the eyes and mucous membranes.

This medicine contains less than 1 mmol sodium (23 mg) per spray, that is to say essentially 'sodium-free'.

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® mouthspray 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® mouthspray 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

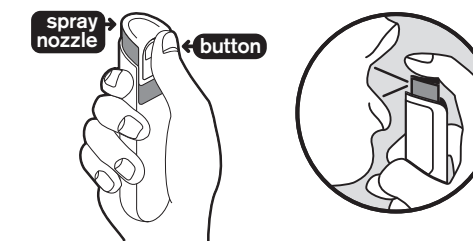
Follow the instructions and study the pictures below to ensure you use NICORETTE® QuickMist correctly. Care should be taken not to spray the eyes whilst administering the spray.

TO UNLOCK NOZZLE



Opening nicorette® QuickMist

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.



Priming nicorette® QuickMist

If you are using NICORETTE® QuickMist for the first time or if you have not used the spray for 2 days, you must first prime the spray pump.

- Point the spray safely away from you and any other adults, children or pets that are near you.
 - Press the top of the QuickMist with your index finger 3 times until a fine spray appears.
- Note: priming reduces the number of sprays you may get from NICORETTE® QuickMist.

How to use nicorette® QuickMist

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 dispenser to release one spray into your mouth. Do not inhale while spraying to avoid getting spray down your throat. For

best results, do not swallow for a few seconds after spraying.

TO LOCK NOZZLE



How to close nicorette® QuickMist

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 QuickMist spray is now closed. Close the QuickMist spray every time after use to prevent use of the spray by children and accidental spraying.

▲ Care should be taken not to spray the eyes whilst administering the mouthspray. **If you get spray in your eye(s), rinse thoroughly with water.**

▲ **Do not eat or drink when administering the mouthspray.**

When to use nicorette® QuickMist

If you are able to stop smoking you should use the mouthspray, when needed, in place of cigarettes. As soon you can (this could be after a number of weeks or months) you should reduce the number of sprays 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 mouthspray. There are toxins in cigarettes that can cause harm to your body.

turn over →

NICORETTE® QuickMist 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 mouthspray 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 mouthspray but are finding this difficult you should contact your doctor, nurse or pharmacist for advice.

Below is the dosage information for nicorette® mouthspray

Children under 12 years

Do not give this product to children under 12 years.

Adults and children aged 12 years and over

Age	Dosage
Adults and children aged 12 years and over	<ul style="list-style-type: none"> It is important to use enough nicotine spray to control cravings. Use one spray first when you would normally smoke a cigarette or have cravings to smoke. If your cravings do not disappear within a few minutes use a second spray. If 2 sprays are required to control cravings, future doses may be delivered as 2 consecutive sprays.

<ul style="list-style-type: none"> Most smokers will require 1 - 2 sprays every 30 minutes to 1 hour. Do not use more than 2 sprays per dose or 4 sprays every hour. Do not use more than 64 sprays per day – this is equivalent to 4 sprays per hour for 16 hours.
<ul style="list-style-type: none"> Do not use more than 2 sprays per dose or more than 64 sprays per day – this is equivalent to 4 sprays every hour for 16 hours.

If you have used too much nicorette® QuickMist

If you have used more than the recommended amount of NICORETTE® QuickMist or have smoked whilst using NICORETTE® QuickMist, 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 has used or swallowed nicorette® QuickMist

Contact a doctor or your nearest hospital Accident and Emergency department immediately if a child under 12 years uses or swallows this medicine. 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®

QuickMist 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® QuickMist before you are ready to reduce your nicotine intake.

These effects include:

- irritability or aggression
- impatient or frustrated
- 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
- constipation
- bleeding gums
- dizziness or light-headedness
- sore throat, stuffy or runny nose

When you stop smoking you may also develop mouth ulcers, cough and/or symptoms of a common cold. The reason why this happens is unknown.

Side-effects for nicorette® QuickMist

If you notice any of the following; fast heart rate/beat, abnormal beating of the heart, palpitations, shortness of breath,

or allergic reactions (swelling of the face mouth, lips, throat and tongue, itching of the skin, swelling of the skin, ulceration and inflammation of the lining of the mouth, difficulty in breathing or dizziness) stop taking NICORETTE® QuickMist and contact a doctor immediately.

Very common side-effects:

(may affect more than 1 in 10 people):

- hiccups (these are particularly common)
- throat irritation
- headache
- feeling sick (nausea)
- cough

Common side-effects:

(may affect up to 1 in 10 people):

- allergic reactions (hypersensitivity)
- burning sensation in the mouth
- dizziness
- taste disturbance or loss of taste
- tingling or numbness of the hands and feet
- toothache
- stomach pain or discomfort
- excessive gas or wind
- vomiting
- dry mouth
- indigestion
- diarrhoea
- tiredness (fatigue)
- sore and inflamed mouth
- increased salivation

Uncommon side-effects:

(may affect up to 1 in 100 people):

- abnormal dream
- sudden reddening of the face and/or neck
- high blood pressure

- sudden constriction of the small airways of the lung that can cause wheezing and shortness of breath
- loss or damage to voice
- throat tightness
- burping (belching)
- swollen red sore tongue
- mouth ulcers or blisters
- numbness or tingling of the mouth
- excessive sweating
- itching
- rash
- hives (urticaria)
- unusual weakness
- chest discomfort and pain
- jaw muscle ache
- general feeling of discomfort or being unwell or out of sorts (malaise)
- dry skin
- muscle and bone pain
- mouth and throat pain
- sneezing
- runny nose
- blocked nose
- inflammation of the gums

Rare side-effects

(may affect up to 1 in 1,000 people):

- difficulty in swallowing
- decreased feeling of sensitivity especially in the mouth
- feeling or wanting to be sick (vomit)

The following side-effects may also occur:

Other side-effects can include:

- blurred vision, watery eyes
- dry throat, lip pain
- stomach discomfort
- redness of the skin
- muscle tightness

If you get any side-effects, talk to your doctor, pharmacist or nurse. This includes any possible side-effects not listed in 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.

You can also report side effects directly in Malta via:

ADR Reporting at:
www.medicinesauthority.gov.mt/adrportal

5 Storing and disposal

- Keep NICORETTE® QuickMist out of the sight and reach 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® QuickMist after the 'Use before' date shown on the back on the pack.
- Dispose of used NICORETTE® QuickMist sensibly and away from children and animals. Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6 Further information

What's in this medicine?

The active ingredient is nicotine.

Other ingredients are: propylene glycol,

anhydrous ethanol, trometamol, poloxamer 407, glycerol, sodium hydrogen carbonate, levomenthol, mint flavour, cooling flavour, sucralose, acesulfame potassium, butylated hydroxytoluene, hydrochloric acid, purified water.

What the medicine looks like

NICORETTE® QuickMist consists of a plastic bottle of solution held in a dispenser with a mechanical spray pump. Each bottle contains 13.2 ml of solution which provides at least 150 sprays, each spray containing 1mg nicotine. NICORETTE® QuickMist is supplied in packs of either 1 or 2 dispensers. Not all pack sizes may be marketed.

Who makes nicorette® QuickMist?

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 July 2018. ©