

Nicorette® QuickMist Mouthspray

Nicotine (1mg/spray)

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What Nicorette® QuickMist is used for

Nicorette® QuickMist is used to help you stop smoking when you want to quit. This is a type of treatment called Nicotine Replacement Therapy (NRT).

How Nicorette® QuickMist works

Nicorette® QuickMist will give you fast relief of your cravings for nicotine and the withdrawal symptoms you get when stopping smoking. When you suddenly stop providing nicotine from tobacco to your body, you get hit by different kinds of unpleasant feelings called withdrawal symptoms.

By using Nicorette® QuickMist you can prevent or reduce these unpleasant feelings and cravings for smoking. This is because you continue to provide a small amount of nicotine to your body for a short of time.

Using Nicorette® QuickMist does not involve the health dangers of tobacco smoking. This is because it does not contain the tar, carbon monoxide or other toxins in cigarette smoke.

To improve the chances of helping you to stop smoking, you should also seek counselling advice and support, if you can.

Before you use Nicorette® QuickMist

-When you must not use it

If you are allergic (hypersensitive) to nicotine or any of the other ingredients in the mouth spray.

-Before you start use it

Contact your doctor if you suffer from the following. You may be able to have

Nicorette® QuickMist, but need to discuss with you doctor first if you have:

- Recently (within 3 months) had a heart attack or stroke
- Chest pain (unstable angina), or resting angina
- A heart condition that effects your heart rate or rhythm
- High blood pressure which is not being controlled by medicines
- Ever had allergic reactions that involve swelling of the lips, face and throat (angioedema) or itchy skin rash (urticaria). Using NRT can sometimes trigger this type of reaction.
- Severe or moderate liver disease
- Severe kidney disease
- Diabetes
- An overactive thyroid gland
- A tumour of the adrenal gland (phaeochromocytoma)
- Stomach ulcer
- Oesophagitis
- Ever had epilepsy (fits)

Nicorette® QuickMist, should not be used by non-smokers.

Pregnancy and breast-feeding

It is very important to stop smoking during pregnancy because it can result in poor growth of your baby. It can also lead to premature births or stillbirths. It is best if you can give up smoking without the use of medicines containing nicotine. If you cannot manage this, Nicorette® QuickMist should only be used after consulting the healthcare professional who is managing your pregnancy, your family doctor, or a doctor in a centre that is specialized in helping people quit smoking.

Nicorette® QuickMist should be avoided during breast-feeding as nicotine is found in breast milk and may affect your child. If your doctor has recommended you to use Nicorette® QuickMist, the spray should be taken just after breast-feeding.

- Taking other medicines

Please tell your doctor or pharmacist if

you are taking or have recently taken any other medicines, including medicines obtained without a prescription. This is especially important if you take medicines containing:
theophylline: to treat asthma
tacrine: for Alzheimer's disease
clozapine: for schizophrenia
ropinirole: to treat Parkinson's disease
flecainide: for heart problems
pentazocine: for severe pain

Do not eat or drink when administering the mouth spray

How to use Nicorette® QuickMist

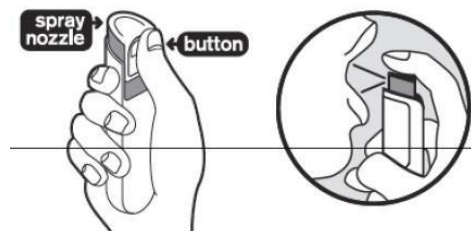
Follow these instructions carefully and use the pictures to guide you

TO UNLOCK NOZZLE



How to open the dispenser

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 load the dispenser

When you use the spray for the first time you must load the spray pump, point the spray nozzle safety away from you, and any other adults, children or pets near you. Press the top of the Nicorette® QuickMist with your index finger 3 times until a fine

Nicorette[®] QuickMist Mouthspray

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spray appears. If you do not use the spray for 2 days, this loading procedure will need to be repeated.

How to use the dispenser

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 few seconds after spraying.

TO RETRACT NOZZLE



How to close the dispenser

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 dispenser 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 mouth spray. If the spray gets into the eyes, rinse thoroughly with water.

- How much to use

Always take Nicorette[®] QuickMist as stated in this package leaflet. You should check with your doctor or pharmacist if you are not sure.

People under 18 years of age should not use Nicorette[®] QuickMist, unless prescribed by a doctor.

You should stop smoking completely during treatment with Nicorette[®] QuickMist. The following chart shows the recommended step by step process for Nicorette[®]

QuickMist

Step 1: 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. The maximum doses 2 sprays at a time, 3 sprays per hour and 48 sprays per day.

Step 2: 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 you used in Step 1.

Step 3: Weeks 10-12

Continue reducing the number of sprays per day so that you are not using more than 3 sprays per day during week 12.

Then stop using Nicorette[®] QuickMist.

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

-When to use it

Always take Nicorette[®] QuickMist as stated in this package leaflet. You should check with your doctor or pharmacist if you are not sure.

-How long to use it

Normally you should take 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.

-If you forget to use it

You should only take Nicorette[®] QuickMist as you need it, following the

dosage instructions above carefully.

-If you use too much (overdose)

Overdosing of nicotine may occur if you smoke at the same time as you take Nicorette[®] QuickMist. If a child takes Nicorette[®] QuickMist or if you have used more Nicorette[®] QuickMist than you should, contact your doctor or go to the nearest hospital immediately. Doses of nicotine that are tolerated by adult smokers during treatment may produce severe symptoms of poisoning in small children and may prove fatal.

The symptoms of overdose are feeling sick (nausea), too much saliva, stomach pain, diarrhoea, sweating, headache, dizziness, changed hearing, and feeling very weak. At high doses, these symptoms may be followed by low blood pressure, weak and irregular pulse, difficulty breathing, extreme tiredness, circulatory collapse and general convulsions.

Administration of nicotine should be stopped temporarily if any symptoms of nicotine excess occur. Nicotine intake should be decreased by either lowering dosing frequency or strength if nicotine excess symptoms persist. If you have any further questions on the use of this product, ask your doctor or pharmacist.

While you are using it

-Things you must do

Use Nicorette[®] QuickMist as instructed. Always inform your doctor or pharmacist if you are using other medicines because some drugs should not be taken together.

-Things you must not do

Never allow others to use medicines recommended for you and never use medicines prescribed for others. Do not eat or drink when administering the mouth spray.

-Things to be careful of

No effects on the ability to drive cars or use machines have been observed.

Side effects

Like all medicines, Nicorette[®]

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QuickMist can cause side effects, although not everybody gets

them. Nicorette[®] QuickMist can give the same side effects as other forms of nicotine. The side effects generally depend on the dose you take.

Effects related to stopping smoking (nicotine withdrawal). Some of the unwanted effects that you experience when stopping smoking can be withdrawal symptoms due to decreases in nicotine intake.

These effects include:

- irritability or aggression
- impatience or frustration
- 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

If you notice any of the following serious rare side effects, stop taking Nicorette[®] QuickMist and contact a doctor immediately (signs of angioedema):

- swollen face, tongue or pharynx
- difficulty to swallow
- hives and difficulties to breath

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, vomiting, sore mouth, throat irritation, dry mouth, taste disturbance, tingling or numbness of hands or feet, stomach pain or discomfort, diarrhoea, wind, cough, burning sensation, fatigue, hypersensitivity.

Uncommonly reported side-effects include

chest palpitations, fast heartbeat, flushing, high blood pressure, redness or itching of the skin, hives, wheezing, shallow breathing, difficulty speaking, nasal congestion, sneezing, tight throat, burping, red tongue, mouth blisters, mouth tingling or numbness, excessive sweating, limb weakness, chest discomfort or pain, general feeling of being unwell, abnormal dreams.

Very rarely, abnormal beating of the heart, swelling of the face, lips mouth or tongue, difficulty swallowing, blurred vision, watery eyes, dry throat lip pain, retching, muscle tightness and seizure have been reported.

When you stop smoking you may also develop mouth ulcers. The reason why this happens is unknown.

If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npa.gov.my [Consumers → Reporting Side Effects to Medicine (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of Nicorette[®] QuickMist

-Storage

Keep out of sight and reach of children. In the event of overdose, get medical help right away. Do not use Nicorette[®] QuickMist

Do not use Nicorette[®] QuickMist after the expiry date which is stated on the dispenser on the blister card. The expiry date refers to the last day of the month unless stated otherwise. Store at temperatures not exceeding 30°C.

-Disposal

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.

Product Description

-What it looks like

Nicorette[®] QuickMist consists of a plastic bottle of solution held in a dispenser with a mechanical spray pump. The dispenser has a child resistant feature. Each bottle contains 13.2 ml of solution which provides

approximately 150 sprays, each containing 1 mg nicotine. Nicorette[®] QuickMist is supplied in packs of either 1 or 2 dispensers.

Not all pack sizes may be marketed.

-Ingredients

-Active ingredient(s)
Nicotine

-Inactive ingredients

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

-MAL number(s):

[MAL23026003ARZ](#)

Manufacturer

McNeil AB,
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Product Registration Holder

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