

**PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE
PHARMACISTS' REGULATIONS (PREPARATIONS) - 1986**

The medicine is dispensed without a doctor's prescription

Nicorette Quick Mist spray 1mg

Oromucosal spray, solution.

Active ingredient -

Nicotine 13.6 mg/ml (nicotine 1 mg per spray)

Inactive and allergenic ingredients: see section 6 "*Further Information*".

Read the leaflet carefully in its entirety before using the medicine. This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor or pharmacist.

Use this medicine in accordance with the instructions in the dosage section in this leaflet. Consult the pharmacist if you need further information. Refer to the doctor if you are still having cravings or are still using Nicorette after 3 months.

1. WHAT IS THE MEDICINE INTENDED FOR?

Nicorette Quick Mist relieves and/or prevents craving and nicotine withdrawal symptoms in nicotine dependence, such as those arising from the use of tobacco or electronic cigarettes. It is indicated in adults, to aid quitting or reduction prior to quitting, to assist those who are unwilling or unable to use such products, and as a safer alternative to smoking tobacco for smokers and those around them.

Nicorette Quick Mist is indicated in pregnant and lactating women making a quit attempt.

NICORETTE® Quick Mist 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 tobacco or vaping, or when cutting down the number of cigarettes/e-cigarettes you smoke/vape.

Therapeutic group: Drug used in nicotine dependence.

Ideally you should always aim to stop smoking and vaping. You can use NICORETTE® Quick Mist spray 1 mg to achieve this by using it to completely replace all your cigarettes/e-cigarettes.

However, NICORETTE® Quick Mist spray 1 mg can also be used in other ways:

- if you feel unable to stop smoking/vaping completely, or wish to replace certain cigarettes/e-cigarettes and therefore it can help you to cut down the number of cigarettes/e-cigarettes you smoke/vape.
- at those times when you can't and do not want to smoke/vape. For example:
 - Where you don't want to smoke/vape 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® Quick Mist do?

When you stop smoking/vaping your body misses the nicotine that you have been absorbing. You may experience unpleasant feelings and a strong desire to smoke/vape (craving). This indicates that you were dependent on nicotine.

When you use NICORETTE® Quick Mist spray 1 mg, 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/vape, but will not give you the "buzz" you get from smoking a cigarette or vaping an e-cigarette.

Benefits you can get from using NRT instead of smoking/vaping

For the best effect, ensure that you use NICORETTE® Quick Mist correctly – see "*HOW SHOULD THE MEDICINE BE USED*".

The benefits of stopping smoking tobacco 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 tobacco/vaping helps relieve feelings of anxiety and stress, but it does not deal with the cause of the stress. In addition, the feeling of relaxation after smoking/vaping 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/e-cigarettes.

- **NRT may benefit** smokers and vapers who want to quit, by helping to **control weight gain** that may be experienced when trying to stop smoking/vaping.

Use of NRT is safer than smoking tobacco but as soon as you are ready, you should aim to stop smoking/vaping completely.

The effects of vaping on your body are not established.

2. BEFORE USING THIS MEDICINE

Do not use the medicine if:

- **you are sensitive (allergic) to the active ingredient or to any of the additional ingredients contained in the medicine (see details in section 6 – "*Further Information*").**
- **you are under 18 years of age.**

Special warnings regarding use of the medicine

- **Before treatment with the medicine, tell the doctor if:**
- **you are pregnant or breast-feeding** you may be able to use nicotine replacement therapy (NRT) to help you give up smoking/vaping but you should try to give up without it. See "*Pregnancy, breastfeeding and fertility*" section.
- **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).

Please act to stop smoking with non-pharmacological interventions. However, if this fails, use of this product may be considered under medical supervision.

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

The risks of continued vaping are not yet established.

- **you have a stomach ulcer**, duodenal ulcer, inflammation of the stomach or inflammation of the oesophagus (passage between the mouth and stomach).
 - **you have liver or kidney disease.**
 - **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.
 - **you have diabetes** – monitor your blood sugar levels more often when starting to use NICORETTE® Quick Mist as you may find your insulin or medication requirements alter.
 - **you are taking any other medicines** such as theophylline, clozapine or ropinirole. Stopping smoking may require the dose of these medicines to be adjusted.
 - **you have ever experienced seizures (fits).**
- **If any of these apply, talk to your doctor, pharmacist or nurse.**

Additional warnings:

- you have quit smoking/vaping and want to stop using the mouth spray but are finding this difficult.

Children and adolescents:

Do not give this product to children under 18 years. There is no experience with the product treatment in this age group. Please refer to section "**If you took an overdose, or if a child has accidentally swallowed the medicine or used it**".

Interactions with other medicines:

If you are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist, especially if you are taking:

other medicines such as theophylline, clozapine, ropinirole or adenosine. Stopping smoking may require the dose of these medicines to be adjusted.

Use of the medicine and food:

Do not eat or drink when administering the mouthspray.

Pregnancy, breastfeeding and fertility:

If you are pregnant:

- 1) **Firstly, you should try to give up smoking/vaping 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, pharmacist or nurse for advice.

The effects of vaping on babies and children are not established.

Products that are used intermittently, including NICORETTE® mouthspray, may be preferable to nicotine patches.

However, patches may be more suitable instead if you have nausea or vomiting.

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/vaping 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, pharmacist or nurse for advice. Take the NICORETTE® mouthspray as soon as possible after breastfeeding 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.

The effects of vaping on your body during pregnancy and breast-feeding are not established. Tobacco smoke produces breathing and other problems in babies and children. The effects of vaping on babies and children are not established.

Driving and using machines

This product has no or negligible influence on the ability to drive and use machines.

Important information about some of the ingredients of the medicine

NICORETTE® Quick Mist contains about 7 mg of alcohol (ethanol) in each spray which is equivalent to 97 mg/ml. The amount in one spray of this medicine is equivalent to less than 2 ml beer or 1 ml wine. The small amount of alcohol in this medicine will not have any noticeable effects.

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'.

3. HOW SHOULD THE MEDICINE BE USED?

Check with the doctor or pharmacist if you are uncertain about the dosage and treatment regimen of the product.

How and when to use this medicine

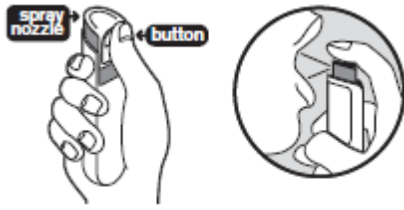
Follow the instructions and study the pictures below to ensure you use NICORETTE® Quick Mist correctly.

Care should be taken not to spray the eyes whilst administering the spray.



Opening Nicorette® Quick Mist

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® Quick Mist

If you are using NICORETTE® Quick Mist 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 Quick Mist with your index finger 3 times until a fine spray appears.

Note: priming reduces the number of sprays you may get from NICORETTE® Quick Mist.

How to use Nicorette® Quick Mist

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® Quick Mist

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 Quick Mist spray is now closed. Close the Quick Mist 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® Quick Mist

If you are able to stop smoking/vaping you should use the mouthspray, when needed, in place of cigarettes/e-cigarettes.

As soon as 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/vaping or do not feel ready to quit at this time, you should replace as many cigarettes/e-cigarettes as possible with the mouthspray. There are toxins in cigarettes that can cause harm to your body.

The effects of vaping on your body are not established.

NICORETTE® Quick Mist provides a safer alternative to smoking tobacco, for both you and those around you. Reducing the amount of cigarettes/e-cigarettes may also help you to

become more motivated to stop smoking/vaping. As soon as you are ready you should aim to stop smoking/ vaping completely.

You can also use the mouthspray on those occasions when you can't or don't want to smoke/vape 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/vaping and want to stop using the mouthspray but are finding this difficult you should contact your doctor, pharmacist or nurse for advice.

The generally accepted dosage is:

Below is the dosage information for Nicorette® mouthspray

Adults

Age	Dosage
Adults above 18 years of age	<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/vape or have cravings to smoke/vape.▪ 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.▪ 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.

Do not exceed the recommended dose.

If you accidentally take a higher dosage

If you have used more than the recommended amount of NICORETTE® Quick Mist or have smoked/vaped whilst using NICORETTE® Quick Mist, you may experience nausea, vomiting, increased 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 you took an overdose, or if a child has accidentally swallowed the medicine or used it, refer immediately to a hospital emergency room, and bring the package of the medicine with you.

Nicotine inhalation or ingestion by a child may result in severe poisoning.

Nicotine in high doses can be very dangerous and sometimes fatal if taken by children.

If you forgot to take the medicine at the required time, do not take a double dose. Take the next dose at the usual time and consult the doctor.

Do not take medicines in the dark! Check the label and the dose each time you take a medicine. Wear glasses if you need them.

If you have further questions regarding use of the medicine, consult the doctor or pharmacist.

4. SIDE-EFFECTS

As with any medicine, use of Nicorette may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not suffer from any of them. As many of the effects are due to nicotine, they can also occur when nicotine is obtained by smoking/vaping.

Effects related to stopping smoking/vaping (nicotine withdrawal)

You may experience unwanted effects because by stopping smoking/vaping you have reduced the amount of nicotine you are taking. You may also experience these effects if you under use NICORETTE® Quick Mist before you are ready to reduce your nicotine intake.

These effects include:

- irritability or aggression
 - feeling 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
 - blurry vision
 - nausea
 - 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® Quick Mist

If you notice any of the following, stop taking NICORETTE® Quick Mist and contact a doctor immediately: fast heart rate/beat, abnormal beating of the heart, palpitations, shortness of breath, seizures (fits), 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).

Very common side-effects:

(effects that occur in more than one user in 10):

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

Common side-effects:

(effects that occur in 1-10 users in 100):

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

Uncommon side-effects:

(effects that occur in 1-10 users in 1,000):

- abnormal dreams
- 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:

(effects that occur in 1-10 users in 10,000):

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

The following unknown frequency 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 a side effect occurs, if one of the side effects worsens or if you suffer from a side effect not mentioned in this leaflet, consult with the doctor.

Side effects can be reported to the Ministry of Health by clicking on the link “Report Side Effects of Drug Treatment” found on the Ministry of Health homepage (www.health.gov.il) that directs you to the online form for reporting side effects, or by entering the link:

<https://sideeffects.health.gov.il>

5. HOW SHOULD THE MEDICINE BE STORED?

- Avoid poisoning! This medicine, and any other medicine, should be kept in a safe place out of the reach and sight of children and/or infants in order to avoid poisoning. Do not induce vomiting without an explicit instruction from the doctor.
- Do not use the medicine after the expiry date (exp. date) that appears on the package and on the bottle. The expiry date refers to the last day of that month.
- Store below 25°C.
- After opening use within 3 months and store below 25°C.
- Dispose of used NICORETTE® Quick Mist 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

In addition to the active ingredient, the medicine also contains:

Propylene glycol, anhydrous ethanol, trometamol, poloxamer 407 (contains butylated hydroxytoluene), glycerol, sodium hydrogen carbonate, levomenthol, mint flavour (contains: ethanol, peppermint oil, glyceryl triacetate E1518, eucalyptus globulus oil, l-menthol), cooling flavour (contains: menthyl glutarates), sucralose, acesulfame potassium, hydrochloric acid, purified water.

What the medicine looks like and the contents of the package:

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 1 mg nicotine.

NICORETTE® QuickMist is supplied in pack of 1 dispenser.

Registration holder: J-C Health Care Ltd., Kibbutz Shefayim 6099000, Israel.

Manufacturer: McNeil AB, Helsingborg, Sweden

Approved in June 2024.

Registration number of the medicine in the National Drug Registry of the Ministry of Health:
175-35-36908-99