

Package leaflet: information for the user
Nicorette QuickMist Cool Berry 1 mg/spray oromucosal spray, solution

Nicotine

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.
- You must talk to a doctor if you have not been able to stop smoking after 6 months of treatment with Nicorette QuickMist Cool Berry.

What is in this leaflet

1. What Nicorette QuickMist Cool Berry is and what it is used for
2. What you need to know before you use Nicorette QuickMist Cool Berry
3. How to use Nicorette QuickMist Cool Berry
4. Possible side effects
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1. What Nicorette QuickMist Cool Berry is and what it is used for

Nicorette QuickMist Cool Berry is used to help you stop smoking when you want to quit or to cut down smoking before stopping completely. This is a type of treatment called Nicotine Replacement Therapy (NRT).

Nicorette QuickMist Cool Berry relieves nicotine withdrawal symptoms including cravings, 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 Cool Berry, 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 period of time. Nicorette QuickMist Cool Berry 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.

2. What you need to know before you use Nicorette QuickMist Cool Berry

Do not use Nicorette QuickMist Cool Berry

- If you are **allergic** to nicotine or any of the other ingredients of this medicine (listed in section 6).
- If you are **under the age of 18 years**.
- If you have **never smoked**.

Warnings and precautions

Talk to your doctor before taking this medicine if you suffer from the following conditions. You may be able to have Nicorette QuickMist Cool Berry, but need to discuss with your 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 or duodenal ulcer**
- **Oesophagitis**

Nicorette QuickMist Cool Berry should not be used by **non-smokers**.

Children and adolescents

Do not give this medicine to children and adolescents.

Other medicines and Nicorette QuickMist Cool Berry

Tell your doctor or pharmacist if you are taking, have recently taken or might take 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

Nicorette QuickMist Cool Berry with food and drink

Do not eat or drink when administering the oromucosal spray.

Pregnancy, breast-feeding and fertility

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 Cool Berry 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 specialised in helping people quit smoking.

Nicorette QuickMist Cool Berry 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 Cool Berry, the spray should be taken just after breast-feeding and not during the 2 hours before breast-feeding.

Smoking increases the risk of infertility in women and men. The effects of nicotine on fertility is unknown.

Driving and using machines

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

Nicorette QuickMist Cool Berry contains 12 mg propylene glycol per spray. This medicine 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 medicinal product also contains less than 1 mmol sodium (23 mg) per spray, i.e. is essentially 'sodium-free'. Due to the presence of butylated hydroxytoluene, Nicorette QuickMist Cool Berry may cause local skin reactions (e.g. contact dermatitis), or irritation to the eyes and mucous membranes.

3. How to use Nicorette QuickMist Cool Berry

Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist have told you. Check with your doctor or pharmacist if you are not sure.

People under **18 years of age** should not use Nicorette QuickMist Cool Berry.

Consult your doctor if you have not achieved a reduction in the number of sprays or in cigarette consumption after 6 weeks of treatment or if you need to use Nicorette QuickMist Cool Berry for longer than 6 months. Normally you should take Nicorette QuickMist Cool Berry for 3 months. Nicorette QuickMist Cool Berry should be taken for no longer than 6 months. Nicorette QuickMist Cool Berry

The instructions about how to use Nicorette QuickMist Cool Berry depend on whether you are stopping smoking immediately or are cutting down the number of cigarettes gradually before stopping completely. Nicorette QuickMist Cool Berry

Stopping smoking immediately

The aim is to stop smoking immediately and use the spray to relieve the cravings to smoke.

Do not use more than 2 sprays at a time or 4 sprays per hour for 16 hours. The maximum dose is 64 sprays over 16 hours in any 24-hour period.

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.

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 4 sprays per day during week 12. When you have reduced to 2-4 sprays per day, you should stop using Nicorette QuickMist Cool Berry.

Stopping smoking gradually

The aim is to start by gradually replacing some of your cigarettes with Nicorette QuickMist Cool Berry. After achieving this, you then stop smoking cigarettes completely while using the spray. Finally, you stop using the spray.

When you feel a strong urge to smoke, use 1-2 sprays instead of a cigarette to help you manage your cravings. The spray is to replace a cigarette, do not smoke shortly after using the spray. Using the spray without reducing your number of cigarettes will make you feel sick (see section 'If you use more Nicorette QuickMist Cool Berry than you should'). Cut down the number of cigarettes you smoke per day, as many as possible and replace them by a spray. If a reduction in cigarette consumption has not been achieved after 6 weeks of treatment, seek the advice from a doctor. As soon as you feel ready, you should quit completely but no later than 12 weeks after start of treatment. After quitting smoking, gradually reduce the number of sprays per day. When you have reduced to 2-4 sprays per day, stop using Nicorette QuickMist Cool Berry. Do not use more than 2 sprays at a time or 4 sprays per hour for 16 hours. The maximum dose is 64 sprays over 16 hours in any 24-hour period.

You may be tempted to smoke again after treatment has stopped. Save any remaining doses of the spray, as craving for smoking may suddenly occur. If you have a craving use one or two sprays if one spray does not help within a few minutes.

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 oromucosal 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 dispenser with your index finger 3 times until a fine 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 **firmly** the top of the dispenser 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.

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 dispenser 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 oromucosal spray. If you get spray in your eye, rinse thoroughly with water.

If you use more Nicorette QuickMist Cool Berry than you should

Overdosing of nicotine may occur if you smoke at the same time as you take Nicorette QuickMist Cool Berry.

If a child takes Nicorette QuickMist Cool Berry or if you have used more Nicorette QuickMist Cool Berry 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 **children** and may prove **fatal**.

The symptoms of overdose are feeling sick (nausea), vomiting, 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.

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

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Nicorette QuickMist Cool Berry 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, aggression, impatience or frustration
- Feeling anxious, restless or having difficulty concentrating
- Night time awakening or sleep disturbance
- Increased appetite or weight gain
- Feeling low
- Urges to smoke (*craving*)
- Lowering of heart rate
- Bleeding gums or mouth ulcers
- Dizziness or light-headedness
- Cough, sore throat, stuffy or runny nose
- Constipation

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

- Swollen face, tongue or pharynx
- Difficulty to swallow
- Hives and difficulties to breath

Very common: may affect more than 1 in 10 people:

- Hiccups (these are particularly common)
- Headache, nausea (feeling sick)
- Throat irritation

Common: may affect up to 1 in 10 people:

- Local effects such as burning sensation, inflammation in the mouth, changes in taste perception

- Dry mouth or increased amounts of saliva
- Feelings of dyspepsia
- Pain or discomfort in tummy (abdomen)
- Vomiting, flatulence or diarrhoea
- Feeling tired (fatigue)
- Hypersensitivity (allergy)
- Tingling
- Cough

Uncommon: may affect up to 1 in 100 people:

- Effects on the nose such as stuffiness, sneezing
- Runny nose
- Wheezing (bronchospasm), or feeling like breathing requires more effort than usual (dyspnoea), throat tightness
- Skin flushing (blushing), or increased sweating
- Oral effects such as mouth tingling, inflammation of the tongue, mouth ulcers, damage to the lining of the mouth, or changes in the sound of your voice, pain in the mouth and throat, belching, bleeding gums.
- Palpitations (an unusual awareness of your heart beating), increase of heart rate, hypertension
- Rash and/or itching (pruritus, urticaria) of the skin
- Abnormal dream
- Chest discomfort and pain
- Weakness, feeling unwell

Rare: may affect up to 1 in 1,000 people

- Difficulty swallowing, reduced sensations in the mouth
- Retching

Not known: frequency cannot be estimated from the available data:

- Blurred vision, increased tear production (lacrimation)
- Dry throat, stomach discomfort, pain in the lips
- Abnormal heart rhythm
- Redness of the skin
- Allergic reactions including swelling of the face and mouth (angioedema or anaphylaxis)

Reporting of side effects

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

You can also report side effects directly via HPRA Pharmacovigilance Website: www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Nicorette QuickMist Cool Berry

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the dispenser and on the blister card. The expiry date refers to the last day of that month.

Do not store above 30°C.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment especially the aquatic environment in the case of nicotine.

6. Contents of the pack and other information

What Nicorette QuickMist Cool Berry contains

- The active substance is nicotine. One spray delivers 1 mg of nicotine.
- The other ingredients are: propylene glycol (E1520), anhydrous ethanol, trometamol, poloxamer 407, glycerol (E422), sodium hydrogen carbonate, levomenthol, red fruits flavour, cooling flavour, sucralose, acesulfame potassium, butylated hydroxytoluene (E 321), hydrochloric acid (for pH adjustment) and purified water.

What Nicorette QuickMist Cool Berry looks like and contents of the pack

Nicorette QuickMist Cool Berry 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 150 sprays.

Nicorette QuickMist Cool Berry is supplied in packs of either 1 or 2 dispensers.

<Nicorette QuickMist Cool Berry is also available in packs of either 1 or 2 dispensers including, underneath the back label, a Near Field Communication (NFC) chip to allow connectivity with a smartphone app. Those dispensers bear this icon



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Not all pack sizes may be marketed.

Explanatory note: The 2 sentences in <> above referring to the presentation with the NFC chip will only be printed on the PL in countries where this presentation is available.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

Johnson & Johnson (Ireland) Limited, Airton Road, Tallaght, Dublin 24, Ireland

Manufacturer:

McNeil AB, P.O. Box 941, Norrbroplatsen 2, SE-251 09 Helsingborg, Sweden

This medicinal product is authorised in the Member States of the EEA under the following names:

Sweden	Nicorette QuickMist Cool Berry
Austria	Nicorette Fruit & Mint Spray
Belgium / The Netherlands	Nicorette Fruit & Mint Mondspray
Bulgaria	Nicorette Berrymint
Croatia	Nicorette s okusom šumskog voća
Cyprus	Nicorette Quickspray Berry
Czech Republic	Nicorette Spray s příchutí lesního ovoce
Denmark	Nicorette QuickMist Cool Berry
Estonia	Nicorette Coolberry Nicorette QuickMist Cool Berry
Finland	Nicorette Berrymint
France	NICORETTESPRAY® FRUITS ROUGES
Germany	Nicorette Fruit & Mint Spray
Greece	Nicorette Quickspray Berry

Hungary	Nicorette Berrymint Nicorette QuickMist Cool Berry
Iceland	Nicorette Quickmist Cool Berry
Ireland	Nicorette QuickMist Cool Berry
Italy	Nicorettequick
Latvia	Nicorette Coolberry
Luxembourg	Nicorette Fruit & Mint Spray Buccal
Norway	Nicorette
Poland	Nicorette QuickMist Cool Berry
Portugal	Nicorette Bucomist sabor fruta menta
Romania	Nicorette Berrymint
Slovak Republic	Nicorette Spray s príchuťou lesného ovocia
Slovenia	Nicorette z okusom gozdnih sadežev
Spain	Nicorette Bucomist sabor fruta menta

For further information on smoking cessation please ring the national smokers quit line on 1800 201 203 or visit www.quit.ie

This leaflet was last revised in