

NICORETTE® QUICKMIST**PATIENT INFORMATION LEAFLET****SCHEDULING STATUS:** S2**NICORETTE® QUICKMIST 1 mg/spray oromucosal spray, solution**

Nicotine (1 mg/spray).

Sugar free.

Contains sweeteners (0,1 mg sucralose and 0,1 mg acesulfame potassium/spray)

Read all of this leaflet carefully because it contains important information for you

NICORETTE® QUICKMIST is available without a doctor's prescription, for you to treat a mild illness. Nevertheless, you still need to use NICORETTE® QUICKMIST carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share NICORETTE® QUICKMIST with any other person.
- Ask your health care provider or pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve after 6 months.

What is in this leaflet

1. What NICORETTE® QUICKMIST is and what it is used for.
2. What you need to know before you use NICORETTE® QUICKMIST.
3. How to use NICORETTE® QUICKMIST.
4. Possible side effects.
5. How to store NICORETTE® QUICKMIST.
6. Contents of the pack and other information.

1. What NICORETTE® QUICKMIST is and what it 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).

NICORETTE® QUICKMIST relieves nicotine withdrawal symptoms including cravings, symptoms you get when stopping smoking. When you suddenly stop providing nicotine from tobacco to your body, you may experience 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 period of time.

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

Do not use NICORETTE® QUICKMIST:

- if you are hypersensitive (allergic) to nicotine or any of the other ingredients of NICORETTE® QUICKMIST (see **What NICORETTE® QUICKMIST contains**)
- if you are under the age of 18 years
- if you have never smoked.

Warning and precautions

Talk to your doctor or health care provider before using NICORETTE® QUICKMIST 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
- **diabetes**
- 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**
- an overactive **thyroid gland**
- a tumour of the **adrenal gland** (phaeochromocytoma)
- **oesophagitis** (painful, difficult swallowing and chest pain with eating)
- a **stomach or duodenal ulcer**
- a history of seizures.

NICORETTE® QUICKMIST should not be used by **non-smokers**.

Other medicines and NICORETTE® QUICKMIST

Always tell your health care provider if you are taking or have recently taken any other medicine.

(This includes all complementary or traditional medicines.)

Tell your doctor or pharmacist if you are currently using:

- **theophylline** (used to treat respiratory diseases such as asthma)
- **clozapine** (use to treat schizophrenia)
- **ropinirole** (used to treat Parkinson's disease).

NICORETTE® QUICKMIST with food, drink and alcohol:

Do not eat or drink when you are administering NICORETTE® QUICKMIST.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before using NICORETTE® QUICKMIST.

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 health care provider who is managing your pregnancy, your family doctor, or a doctor that specialises in helping people quit smoking.

NICORETTE® QUICKMIST should be avoided during breastfeeding as nicotine is found in breast milk and may affect your child. If your doctor has recommended the use of NICORETTE® QUICKMIST, the spray should be taken just after breastfeeding and not during the 2 hours before breastfeeding.

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

Driving and using machines

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

NICORETTE® QUICKMIST contains propylene glycol, ethanol and butylated hydroxytoluene

NICORETTE® QUICKMIST contains 11 mg propylene glycol per spray and less than 100 mg per dose (1 or 2 sprays) alcohol (ethanol). Due to the presence of butylated hydroxytoluene, NICORETTE® QUICKMIST may cause local skin reactions (e.g. contact dermatitis), or irritation to the eyes and mucous membranes.

3. How to use NICORETTE® QUICKMIST

Always use NICORETTE® QUICKMIST 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.

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.

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 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 I.

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.

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.

Normally you should take NICORETTE® QUICKMIST for 3 months, though no longer than 6 months.

Consult your doctor if you need to use NICORETTE® QUICKMIST for longer than 6 months.

Follow these instructions carefully and use the pictures to guide you.

To unlock the 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 NICORETTE® QUICKMIST 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 the 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 NICORETTE® QUICKMIST. If you get spray in your eye, rinse thoroughly with water.

If you use more NICORETTE® QUICKMIST than you should

Overdosing of nicotine may occur if you smoke at the same time as you are using 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 **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 health care provider or pharmacist.

4. Possible side effects

NICORETTE® QUICKMIST can have side effects.

Not all side effects reported for NICORETTE® QUICKMIST are included in this leaflet. Should your general health worsen or if you experience any untoward effects while using NICORETTE® QUICKMIST, please consult your health care provider for advice. 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, aggression, impatience or frustration
- feeling anxious, restless or having difficulty concentrating
- night-time awakening or sleep disturbances
- increased appetite or weight gain
- feeling low
- urges to smoke (cravings)
- lowering of heart rate
- bleeding gums or mouth ulcers
- dizziness or light-headedness

- cough, sore throat, stuffy or runny nose
- constipation.

If any of the following happens, stop using NICORETTE® QUICKMIST and contact your doctor immediately or go to the casualty department at your nearest hospital (signs of angioedema or anaphylaxis):

- allergic reactions including swollen face, mouth, tongue or throat
- difficulty swallowing
- hives and difficulty breathing.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to NICORETTE® QUICKMIST.

You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- increased heart rate, abnormal heart rhythm, palpitations (an unusual awareness of your heart beating).

These are serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent side effects:

- hiccups
- headache, nausea (feeling sick)
- throat irritation
- local effects such as burning sensation, inflammation in your mouth, changes in your taste perception
- dry mouth or increased amounts of saliva
- indigestion

- pain or discomfort in your tummy (abdomen)
- vomiting, flatulence or diarrhoea
- feeling tired (fatigue)
- hypersensitivity (allergy)
- tingling.

Less frequent side effects:

- effects on the nose such as stuffiness, sneezing
- 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 your tongue, mouth ulcers, damage to the lining of your mouth, or changes in the sound of your voice, pain in your mouth and throat, belching
- high blood pressure
- rash and/or itching (pruritus, urticaria) of your skin
- abnormal dream
- chest discomfort and pain
- weakness, feeling unwell
- bleeding gums
- runny nose.

Frequency unknown side effects:

- blurred vision, increased tear production (lacrimation)
- dry throat, stomach discomfort, lip pain
- redness of the skin.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or

pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist. You can also report side effects to SAHPRA via the “6.04 Adverse Drug Reactions Reporting Form”, found online under SAHPRA’s publications: <http://www.sahpra.org.za/Publications/Index/8>.

By reporting side effects, you can help provide more information on the safety of NICORETTE® QUICKMIST.

For further information, please contact the Johnson and Johnson call centre on 0860 410032 (landline).

5. How to store NICORETTE® QUICKMIST

- Keep all medicines out of reach of children.
- Do not store above 30 °C.
- Do not use this medicine after the expiry date printed on the carton and the dispenser.
- Return all unused medicine to your pharmacist.
- Do not throw away any medicines via wastewater or household waste. These measures will help to protect the environment.

6. Contents of the pack and other information

What NICORETTE® QUICKMIST 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, mint flavour, cooling flavour, sucralose, acesulfame potassium, butylated hydroxytoluene (E321), hydrochloric acid (for pH adjustment) and purified water.

What NICORETTE® QUICKMIST looks like and contents of the pack

NICORETTE® QUICKMIST consists of a transparent plastic bottle of solution held in a dispenser with a mechanical pump. The dispenser has a child resistant feature. Each bottle contains 13,2 mL of a clear to slightly milky, colourless to light yellow solution which provides 150 sprays.

NICORETTE® QUICKMIST is supplied in packs of either 1 or 2 dispensers.

Not all pack sizes may be marketed.

Holder Of Certificate Of Registration

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