

Project Name / Design | FG90117602 Brochure/Leaflet/Insert Nicorette Nicorine QuickMist 150mg MY AsiaPac_2023_00091429_000 old Component / Item Code Product / Eurocode / Mat. ID Code 90117602 Job / Version No. 403223003_r0 Date 14-03-2023



	REPRESENTATION: 🔼 Colours represented with a diagonal line have been modified to aid PDF approval.						
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	Reference CH020040		Technical Code	652348			
	Substrate	Substrate WHITE		PC-Spec	PC-0002669 (no tag) PC-0010677 (with RF tag)		
	Braille Nr	Braille Nr N/A		Colour Target Ref	N/A		
ı	TECHNICA	AL DETAILS					
	Component	Component Leaflet		Plant	Helsingborg		
	Dimensions	558 x 179 mm (Folded 45	x 70 mm)	Master Dieline	JJSC_00229_V5	Date 20-11-2022	
	Profile	Text Limit	Bleed	Fold/Technical	Perforation	Stamping Area	
	Coding (Silent Z	one) Print & Varnish Free	Print Free	Varnish Free	Seal Area	Tamper Evident Label Area	

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BARCODE @ 48%



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← 27.554 mm → **←** 30 mm → This PIL is not intended for Malaysia consumers, please refer to Malaysia approved Patient Information Leaflet in NPRA website. Malaysia approved Package Insert is included in the

product.

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

You need to use Nicorette® QuickMist carefully to get the best results from it.

- · Keep this leaflet. You may need to read it
- Ask your pharmacist if you need more information or advice.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.
- Contact your doctor or pharmacist if you have not been able to stop smoking after 6 months of treatment with Nicorette® QuickMist.



McNeil Sweden AB

In this leaflet:

- 1. What Nicorette® QuickMist is and what it is used for
- 2. Before you take Nicorette® QuickMist
- 3. How to take Nicorette® QuickMist
- 4. Possible side effects 5. How to store Nicorette® QuickMist
- Further information

WHAT NICORETTE® QUICKMIST IS AND WHAT IT IS USED FOR

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

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 period of time. Using Nicorette® QuickMist does not involve the health - Ever experienced seizure (fits) dangers of tobacco smoking. This is because it does not contain the tar, carbon monoxide or other toxins in cigarette smoke.

o improve the chances of helping you to stop smoking, you should also seek counselling advice Please tell your doctor or pharmacist if you are and support, if you can.

BEFORE YOU TAKE NICORETTE® QUICKMIST

Do not use Nicorette® QuickMist

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

Take special care with Nicorette® QuickMist

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- Contact your doctor if you suffer from the following. You may be able to have Nicorette® QuickMist, but need to discuss with your doctor
- first if you have: - Recently (within 3 months) had a **heart attack** of your baby. It can also lead to premature births
- or stroke
- Ever had **allergic reactions** that involve swelling of the lips, face and throat
- Severe kidney disease
- An overactive thyroid gland
- Stomach ulcer

Nicorette® QuickMist should not be used by non-smokers

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

pentazocine for severe pain

ropinirole to treat Parkinson's disease **flecainide** for heart problems

Do not eat or drink when administering the mouth

healthcare professional who is managing your

pregnancy, your family doctor, or a doctor in a

centre that is specialised in helping people guit

Nicorette® QuickMist should be avoided during

milk and may affect your child. If your doctor has

recommended you to use Nicorette® QuickMist,

breast-feeding as nicotine is found in breast

No effects on the ability to drive cars or use

Important information about some of the

ethanol (alcohol), less than 100 mg per spray.

package leaflet. You should check with your

People under **18 years of age** should not use

Nicorette® QuickMist, unless prescribed by a

You should stop smoking completely during

treatment with Nicorette® QuickMist.

doctor or pharmacist if you are not sure.

This medicinal product contains small amounts of

ingredients in Nicorette® QuickMist

the spray should be taken just after

Driving and using machines

machines have been observed.

■ NICORETTE® QUICKMIST

breast-feeding.

♠ HOW TO TAKE

Pregnancy and breast-feeding It is very important to stop smoking during

- Chest pain (unstable angina), or resting angina If you cannot manage this, Nicorette® QuickMist A **heart condition** that effects your heart rate should only be used after consulting the
- **High blood pressure** which is not being controlled by medicines
- (angioedema) or itchy skin rash (urticaria). Using NRT can sometimes trigger this type of
- Severe or moderate **liver disease**
- Diabetes
- A tumour of the adrenal gland (phaeochromocytoma)
- Oesophagitis

Using other medicines

The following chart shows the recommended step by step process for Nicorette® QuickMist.

doctor.

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 **pregnancy** because it can result in poor growth spray. If 2 sprays are required, future doses may be delivered as 2 consecutive sprays. For or stillbirths. It is best if you can give up smoking most smokers this means about 1 or 2 sprays without the use of medicines containing nicotine.

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 dose is 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 spray does not help within a few minutes.

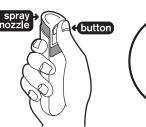
Normally vou should take Nicorette® QuickMist f 3 months, though no longer than 6 months. Always take Nicorette® QuickMist as stated in this Consult your doctor or pharmacist if you need to use Nicorette® QuickMist for longer than 6 months. Save any remaining doses of the spray, as craving for smoking may suddenly occur.

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



How to load the dispenser

When you use the 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 QuickMist 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

How to use the dispenser

- 3. Point the spray nozzle towards your open mouth and hold it as close to your mouth as
- 4. Press the top of the 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 a few seconds after spraying.

TO RETRACT NOZZLE



ow to close the dispense

- 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.

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 your eyes, rinse thoroughly with water.

If you use more Nicorette® QuickMist than you impatience or frustration should

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, poor concentration contact your doctor or go to the nearest hospital • increased appetite or weight gain **immediately.** Doses of nicotine that are tolerated • urges to smoke (craving) by adult smokers during treatment may produce
• night time awakening or sleep disturbance 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.

POSSIBLE 4 SIDE EFFECTS

Like all medicines, Nicorette® 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

- restlessness

- 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

continue

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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.

5 HOW TO STORE NICORETTE® QUICKMIST

Keep out of sight and reach of children. In the event of overdose, get medical help right away.

Do not use Nicorette® QuickMist 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 unless stated otherwise.

Reg.No 1C 15008/66 (N)
Tel.1800-333-666 (Toll free expiry date which is stated on the dispenser and on the blister card. The expiry date refers to the last day of that month unless stated otherwise.

Store at temperatures not exceeding 30°C

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 Nicorette® QuickMist contains

- The active substance is nicotine. One spray dose contains 1 mg of nicotine.
- The other ingredients are: 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.

What Nicorette® QuickMist looks like and contents of the pack

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.

Product Registration Holder:

Johnson & Johnson (Thailand) Ltd.

Bangkok, Thailand.

Reg.No 1C 15008/66 (N)

Tel.1800-333-666 (Toll free except hand phone)

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