nicorette

and QuickMist SmartTrack™ 1mg/spray mouthspray

What should you know about nicorette® QuickMist mouthspray

(nicotine 1 mg per spray)

Please read this leaflet carefully before you start using this medicine. It provides useful information on how to use it safely. Keep the leaflet, you might need it again.

If you think you are having side-effects, have any questions or are not sure about anything please ask your doctor. pharmacist or nurse.

nicorette

QuickMist 1mg/spray mouthspray and QuickMist SmartTrack 1mg/spray mouthspray

PACKAGE LEAFLET: INFORMATION FOR THE USER



1 What this medicine is for NICORETTE® QuickMist 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.

Ideally you should always aim to stop smoking and vaping. You can use NICORETTE® mouthspray to achieve this by using it to completely replace all your cigarettes/e-cigarettes. However NICORETTE® mouthspray 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 guit attempt a behavioural support programme will increase your chances of success.

What does nicorette® QuickMist 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® QuickMist. 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® QuickMist correctly - see "How to Use NICORETTE® QuickMist."

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, cvanide 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 nicorette® OuickMist:
- if you have an allergy to nicotine or any of the other ingredients.
- if you are under 12 years of age.

A Talk to your doctor, pharmacist or nurse...

- 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 "If you are pregnant or breast-feeding"
- if you are in hospital because of heart disease (including heart attack. chest pain, disorders of heart rate or rhythm, angina, high blood pressure or

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.

- if you have a stomach ulcer. duodenal ulcer, inflammation of the stomach or inflammation of the oesophagus (passage between the mouth and stomach).
- if you have liver or kidney disease.
- if 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.

- if vou have diabetes monitor your blood sugar levels more often when starting to use NICORETTE® QuickMist as you may find your insulin or medication requirements alter.
- if you are taking any other medicines such as theophylline, clozapine or ropinirole. Stopping smoking may require the dose of these medicines to be adjusted.
- ■if you have ever experienced seizures (fits).
- if you have guit smoking/vaping and want to stop using the mouth spray but are finding this difficult.
- ➤ If any of these apply, talk to your doctor, pharmacist or nurse.

A Important information about some of the ingredients

NICORETTE® QuickMist 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

This medicine contains 11 mg propylene glycol in each spray which is equivalent to 150 ma/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'.

A If you are pregnant or breast-feeding

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 guicker 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 is 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 sickness. 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, vou are best to use NRT products that are taken intermittently (not patches), however you should talk to vour doctor, pharmacist or nurse for advice. Breast-feed just before you use NICORETTE® mouthspray to ensure that the baby gets the smallest amount of nicotine possible. If you do need to use NRT to help you

guit, 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 is not established

3 How and when to use this medicine

Follow the instructions and study the pictures below to ensure you use NICORETTE® QuickMist correctly. Care should be taken not to spray the eves whilst administering the spray.

TO UNLOCK NOZZLE

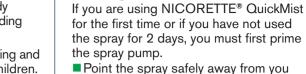






- 1.Use your thumb to slide down the button (a) until it can be pushed lightly inwards (b). Do not push too hard.
- 2. While pushing in, slide upwards (c) to unlock the top of the dispenser. Then release the button.

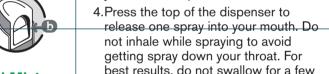




and any other adults, children or pets that are near you. Press the top of the QuickMist with











seconds after spraving.

• Priming nicorette® QuickMist

your index finger 3 times until a fine

Note: priming reduces the number

How to use nicorette® QuickMist

3. Point the spray nozzle towards your

open mouth and hold it as close to

of sprays you may get from

NICORETTE® QuickMist.

vour mouth as possible.

spray appears.



O How to close nicorette® QuickMist

- 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. Close the QuickMist spray every time after use to prevent use of the spray

turn over →



402663758 r7.indd 1 06/10/2022 10:23 AM by children and accidental spraying.

A 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® QuickMist

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

NICORETTE® QuickMist 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.

not established.

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.

- Below is the dosage information for nicorette® mouthspray
- Children under 12 years

 Do not give this product to children under 12 years.
- Adults and children aged 12 years and over

| Age Dosage Adults and children aged 12 years and over 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 per day – this is equivalent to 4 sprays per dose or more than 64 sprays per day – this is equivalent to 4 sprays per day – this is equivalent to 4 sprays every | | |
|--|----------------------------------|--|
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| | | |

▲ If you have used too much nicorette® QuickMist

hour for 16 hours.

If you have used more than the recommended amount of NICORETTE® QuickMist or have smoked/vaped whilst using NICORETTE® QuickMist, you may experience nausea (feeling sick).

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 a child has used or swallowed nicorette® QuickMist

Contact a doctor or your nearest hospital Accident and Emergency department immediately if a child under 12 years uses or swallows this medicine. Take this leaflet and the pack with you.

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

Using nicorette® QuickMist SmartTrack

The NICORETTE® QuickMist SmartTrack™ mouthspray helps you track your usage by holding it against your phone after each spray. It uses Near Field Communication (NFC) technology to send information to the NICORETTE® app. This is to help you track your progress on your quit smoking/vaping journey. Please refer to the inside panel of the packaging for detailed usage instructions.

4 Possible side-effects

Like all medicines, NICORETTE® QuickMist can have side-effects. 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® QuickMist before you are ready to reduce your nicotine intake.

10 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® OuickMist

If you notice any of the following: 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) stop taking NICORETTE® QuickMist and contact a doctor immediately.

Very common side-effects:

(may affect more than 1 in 10 people):

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

Common side-effects:

(may affect up to 1 in 10 people):

- 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 or discomfort
- excessive gas or wind
- vomiting
- dry mouth
- indigestion
- diarrhoea
- tiredness (fatigue)sore and inflamed mouth
- ■increased salivation

Uncommon side-effects:

(may affect up to 1 in 100 people):

- ■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 iaw 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

(may affect up to 1 in 1,000 people):

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

The following side-effects may also occur:

- Other side-effects can include:
- blurred vison, watery eyesdrv throat. lip pain
- stomach discomfort
- redness of the skin
 muscle tightness
- ➤ If you get any side-effects, talk to your doctor, pharmacist or nurse. This includes any possible side-

effects not listed in this leaflet. You can also report side-effects directly via the Yellow Card Scheme at:

www.mhra.gov.uk/yellowcard
or search for MHRA Yellow Card in the Google Play or Apple App Store.

By reporting side-effects you can help provide more information on the safety of this medicine.

5 Storing and disposal

- Keep NICORETTE® QuickMist out of the sight and reach of children and animals. Nicotine in high doses can be very dangerous and sometimes fatal if taken by children.
- Do not store above 30° C.
- Do not use NICORETTE® QuickMist after the 'Use before' date shown on the back on the pack.
- Dispose of used NICORETTE®
 QuickMist 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

What's in this medicine? The active ingredient is nicotine.

Other ingredients are: propylene glycol, anhydrous ethanol, trometamol, poloxamer 407, glycerol, sodium hydrogen carbonate, levomenthol, mint flavour, cooling flavour, sucralose, acesulfame potassium, butylated hydroxytoluene, hydrochloric acid, purified water.

What the medicine looks like 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

XXXXXX

which provides at least 150 sprays, each spray containing 1mg nicotine.

NICORETTE® QuickMist is supplied in packs of either 1, 2, 3, 4 or 6 dispensers.

Not all pack sizes may be marketed.

Who makes nicorette® QuickMist?

The Product Licence holder is McNeil Products Ltd, 50 -100 Holmers Farm Way, High Wycombe, Buckinghamshire, HP12 4EG, UK. The manufacturer is McNeil AB, Helsingborg, Sweden.

This leaflet was prepared in October 2022.

McNeil Products Limited 2022 ©

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nicorette

QuickMist 1mg/spray mouthspray and QuickMist SmartTrack™ 1mg/spray mouthspray

What should you know about nicorette® QuickMist mouthspray

(nicotine 1 mg per spray)

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PACKAGE LEAFLET:
INFORMATION FOR THE USER



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- ■NRT may benefit smokers and vapers who want to quit, by helping to control

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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

- If you have an allergy to nicotine or any of the other ingredients.
- if you are under 12 years of age.
- ▲ Talk to your doctor, pharmacist or nurse...
- 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
 "If you are pregnant or breast-feeding"
 section.
- if 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). 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.
- if you have a stomach ulcer, duodenal ulcer, inflammation of the stomach or inflammation of the oesophagus (passage between the mouth and stomach).
- if you have liver or kidney disease.
- if you have an overactive thyroid gland or have a phaeochromocytoma (a tumour of the adrenal gland that can

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- if you are taking any other medicines such as theophylline, clozapine or ropinirole. Stopping smoking may require the dose of these medicines to be adjusted.
- if you have ever experienced seizures (fits).
- if you have quit smoking/vaping and want to stop using the mouth spray but are finding this difficult.
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This medicine contains less than 1 mmol sodium (23 mg) per spray, that is to say essentially 'sodium-free'.

A If you are pregnant or breast-feeding

If you are pregnant:

- 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 is 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 sickness. If you do use patches take

If you are breast-feeding:

1) Firstly, you should try to give up smoking/vaping without NRT.

them off before going to bed at night.

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. Breast-feed just before you use NICORETTE® mouthspray 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 is not established.

3 How and when to use this medicine

Follow the instructions and study the pictures below to ensure you use NICORETTE® QuickMist correctly. Care should be taken not to spray the eyes whilst administering the spray.

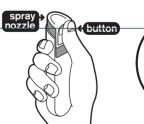
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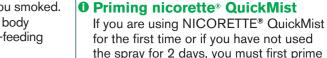




Opening nicorette® QuickMist

- 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.





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 QuickMist with your index finger 3 times until a fine spray appears.
Note: priming reduces the number of sprays you may get from

• How to use nicorette® QuickMist

Point the spray nozzle towards your open mouth and hold it as close to your mouth as possible.

NICORETTE® QuickMist.

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® QuickMist

- 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. Close the QuickMist spray every time after use to prevent use of the spray by children and accidental spraying.

turn over →



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- A 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® QuickMist

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 guit at this time.

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.

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+ + + + + + + + + + + + +

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A--- D-----

| Age | Dosage | ı |
|--|---|---|
| Adults and
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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. | |
| | e more than 2 sprays per
nore than 64 sprays per day | |

▲ If you have used too much nicorette® QuickMist

hour for 16 hours.

If you have used more than the recommended amount of NICORETTE® QuickMist or have smoked/vaped whilst using NICORETTE® QuickMist, you may experience nausea (feeling sick).

- this is equivalent to 4 sprays every

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.

A If a child has used or swallowed nicorette® QuickMist

Contact a doctor or your nearest hospital Accident and Emergency department immediately if a child under 12 years uses or swallows this medicine. Take this leaflet and the pack with you.

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

Using nicorette[®] QuickMist SmartTrack[™]

The NICORETTE® QuickMist SmartTrack™ mouthspray helps you track your usage by holding it against your phone after each spray. It uses Near Field Communication (NFC) technology to send information to the NICORETTE® app. This is to help you track your progress on your quit smoking/vaping journey. Please refer to the inside panel of the packaging for detailed usage instructions.

4 Possible side-effects

Like all medicines, NICORETTE® QuickMist can have side-effects. 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® QuickMist before you are ready to reduce your nicotine intake.

O These effects include:

- ■irritability or aggression
- feeling impatient or frustrated
- feeling low
- anxiety
- restlessness
- poor concentrationincreased 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® OuickMist

If you notice any of the following: 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 breathing or dizziness) stop taking NICORETTE® QuickMist and contact a doctor immediately.

Very common side-effects:

(may affect more than 1 in 10 people):

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

Common side-effects:

(may affect up to 1 in 10 people):

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

Uncommon side-effects:

(may affect up to 1 in 100 people):

- ■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 tonguemouth 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

(may affect up to 1 in 1,000 people):

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

The following side-effects may also occur:

Other side-effects can include:

- blurred vison, watery eyesdry throat, lip pain
- stomach discomfort
- redness of the skin muscle tightness
- ➤ If you get any side-effects, talk to your doctor, pharmacist or nurse. This includes any possible side-

effects not listed in this leaflet. You can also report side-effects directly via the Yellow Card Scheme at:

www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side-effects you can help provide more information on the safety of this medicine.

5 Storing and disposal

- Keep NICORETTE® QuickMist out of the sight and reach of children and animals. Nicotine in high doses can be very dangerous and sometimes fatal if taken by children.
- Do not store above 30° C.
- Do not use NICORETTE® QuickMist after the 'Use before' date shown on the back on the pack.
- Dispose of used NICORETTE®

 QuickMist 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

What's in this medicine?

The active ingredient is nicotine.

Other ingredients are: propylene glycol, anhydrous ethanol, trometamol, poloxamer 407, glycerol, sodium hydrogen carbonate, levomenthol, mint flavour, cooling flavour, sucralose, acesulfame potassium, butylated hydroxytoluene, hydrochloric acid, purified water.

What the medicine looks like
NICORETTE® QuickMist consists of a
plastic bottle of solution held in a
dispenser with a mechanical spray

which provides at least 150 sprays, each spray containing 1mg nicotine.

NICORETTE® QuickMist is supplied in packs of either 1, 2, 3, 4 or 6 dispensers.

Not all pack sizes may be marketed.

Fach bottle contains 13.2 ml of solution

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Who makes nicorette® QuickMist?

The Product Licence holder is McNeil Products Ltd, 50 -100 Holmers Farm Way, High Wycombe, Buckinghamshire, HP12 4EG, UK. The manufacturer is McNeil AB, Helsingborg, Sweden.

This leaflet was prepared in October 2022.

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nicorette

QuickMist 1mg/spray mouthspray

What should you know about nicorette® QuickMist mouthspray (nicotine 1 mg per spray)

Please read this leaflet carefully before you start using this medicine. It provides useful information on how to use it safely. Keep the leaflet, you might need it again.

If you think you are having side-effects, have any questions or are not sure about anything please **ask your doctor**, **pharmacist or nurse**.

nicorette

QuickMist 1mg/spray mouthspray

PACKAGE LEAFLET:
INFORMATION FOR THE USER

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1 What this medicine is for NICORETTE® QuickMist 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.

Ideally you should always aim to stop smoking and vaping. You can use NICORETTE® mouthspray to achieve this by using it to completely replace all your cigarettes/e-cigarettes. However NICORETTE® mouthspray 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 guit.

When making a quit attempt a behavioural support programme will increase your chances of success.

What does nicorette® QuickMist 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® QuickMist, 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® QuickMist correctly – see "How to Use NICORETTE® QuickMist."

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. 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 yet established.

2 Before using this medicine

any of the other ingredients.

- If you have an allergy to nicotine or
- if you are under 12 years of age.
- ▲ Talk to your doctor, pharmacist or nurse...
- 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 "If you are pregnant or
 breast-feeding" section.
- if 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).

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.

- if you have a stomach ulcer, duodenal ulcer, inflammation of the stomach or inflammation of the oesophagus (passage between the mouth and stomach).
- if you have liver or kidney disease.
- if 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.
- if you have diabetes monitor your blood sugar levels more often when

starting to use NICORETTE®

QuickMist as you may find your insulin or medication requirements alter.

- if you are taking any other medicines such as theophylline, clozapine or ropinirole. Stopping smoking may require the dose of these medicines to be adjusted.
- if you have ever experienced seizures (fits).
- If you have quit smoking/vaping and want to stop using the mouth spray but are finding this difficult.
- ➤ If any of these apply, talk to your doctor, pharmacist or nurse.

▲ Important information about some of the ingredients

NICORETTE® QuickMist 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'.

A If you are pregnant or breast-feeding

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,

vou 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 is 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 sickness. 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. Breast-feed just before you use NICORETTE® mouthspray 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 is not established.

3 How and when to use this medicine

Follow the instructions and study the pictures below to ensure you use NICORETTE® QuickMist correctly. Care should be taken not to spray the eyes whilst administering the spray.

TO UNLOCK NOZZLE







• Opening nicorette® QuickMist

- 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® QuickMist

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

 Note: priming reduces the number of sprays you may get from

NICORETTE® QuickMist.

• How to use nicorette® QuickMist

- 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® QuickMist

- 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. Close the QuickMist 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.

turn over →

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▲ Do not eat or drink when administering the mouthspray.

When to use nicorette® QuickMist

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® QuickMist 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

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 attempt behavioural therapy advice and support will normally improve the attempt behavioural therapy advice and support will normally improve the attempt behavioural therapy advice and support will normally improve the attempt behavioural therapy advice and support will normally improve the attempt behavioural therapy advice and support will normally improve the attempt behavioural therapy advice and support will normally improve the attempt behavioural therapy advice and support will normally improve the attempt behavioural therapy advice and support will normally improve the attempt behavioural therapy advice and support will normally improve the attempt behavioural therapy advice and support will normally improve the attempt behavioural therapy advice and support will normally improve the attempt behavioural therapy advice and support will normally improve the attempt behavioural therapy advice and support will normally improve the attempt behavioural therapy advice and support will normally improve the attempt behavioural therapy advice and support will normally improve the attempt behavioural therapy advice and support will normally improve the attempt behavioural therapy advice and support will normally improve the attempt behavioural therapy advice and support will normally improve the attempt behavioural therapy advice and support will normally improve the attempt behavioural therapy advice and support will normally improve the attempt behavioural therapy advice and support will normally improve the attempt behavioural therapy advice and support will normally improve the attempt behavioural therapy advice and support will normally improve the attempt behav

• Below is the dosage information for nicorette® mouthspray

• Children under 12 years

Do not give this product to children under 12 years.

• Adults and children aged 12 years and over

Dosage

| Adults and
children
aged 12
years and
over | It is important to use enougnicotine 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 spra |
| | 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.

- this is equivalent to 4 sprays every hour for 16 hours. A If you have used too much

dose or more than 64 sprays per day

■ Do not use more than 2 sprays per

nicorette® QuickMist

If you have used more than the recommended amount of NICORETTE® QuickMist or have smoked/vaped whilst using NICORETTE® QuickMist, you may experience nausea (feeling sick), yomiting, increased salivation, pain in

your abdomen, diarrhoea, sweating, headache, dizziness, hearing disturb

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.

A If a child has used or swallowed nicorette® QuickMist

Contact a doctor or your nearest hospital Accident and Emergency department immediately if a child under 12 years uses or swallows this medicine. Take this leaflet and the pack with you.

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

4 Possible side-effects

Like all medicines, NICORETTE®

QuickMist can have side-effects. 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® QuickMist before you are ready to reduce your nicotine intake.

• These effects include:

irritability or aggressionfeeling impatient or frustratedfeeling low

anxiety

restlessness

poor concentration

increased appetite or weight gain

urges to smoke (craving)

- night time awakening or sleep disturbance
- ■lowering of heart rate
- constipationbleeding 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® QuickMist

If you notice any of the following: 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) stop taking NICORETTE® QuickMist and contact a doctor immediately.

Very common side-effects:

(may affect more than 1 in 10 people):

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

Common side-effects:

(may affect up to 1 in 10 people):

- 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 or discomfort
- excessive gas or wind
- dry mouth
- indigestion
- ■diarrhoea
- tiredness (fatigue)
- sore and inflamed mouth
- ■increased salivation

Uncommon side-effects:

(may affect up to 1 in 100 people):

- 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)
- nives (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
- runny nose
- ■blocked nose
- ■inflammation of the gums

Rare side-effects

(may affect up to 1 in 1,000 people):

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

The following side-effects may also occur:

Other side-effects can include:

- blurred vison, watery eyes
- dry throat, lip pain stomach discomfort
- redness of the skin
- muscle tightness
 If you get any side-effects, talk to your doctor, pharmacist or nurse.
 This includes any possible side-effects not listed in this leaflet. You can also report side-effects directly via the Yellow Card Scheme at:
- www.mhra.gov.uk/yellowcard
 or search for MHRA Yellow Card in
 the Google Play or Apple App Store.
 By reporting side-effects you can
 help provide more information on
 the safety of this medicine.

5 Storing and disposal

■ Keep NICORETTE® QuickMist out

of the sight and reach of children and animals. Nicotine in high doses can be very dangerous and sometimes fatal if taken by children.

- Do not store above 30° C.
- Do not use NICORETTE® QuickMist after the 'Use before' date shown on the back on the pack.
- Dispose of used NICORETTE®

 QuickMist 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.

QuickMist? Product Licence holder and Manufacturer: McNeil Products Ltd, 50-100 Holmers Farm Way,

Who makes nicorette®

High Wycombe, Buckinghamshire, HP12 4EG, UK. This leaflet was prepared in October 2022.

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6 Further information What's in this medicine?

The active ingredient is nicotine.

Other ingredients are: propylene glycol, anhydrous ethanol, trometamol, poloxamer 407, glycerol, sodium hydrogen carbonate, levomenthol, mint flavour, cooling flavour, sucralose, acesulfame potassium, butylated hydroxytoluene, hydrochloric acid, purified water.

What the medicine looks like

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 1mg nicotine.

NICORETTE® QuickMist is supplied in packs of 1, 2, 3, 4 or 6 dispensers.

Not all pack sizes may be marketed.

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