

PACKAGE LEAFLET

Package leaflet : Information for the user

NiQuitin Mint 2 mg lozenges NiQuitin Mint 4 mg lozenges

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 healthcare professional told you.

- Keep this leaflet. You may need to read it again.
- Ask a healthcare professional e.g. doctor, nurse, smoking cessation adviser or pharmacist if you need more information or advice.
- If you get any side effects, talk to your healthcare professional. 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 NiQuitin Mint.
- Throughout this leaflet NiQuitin Mint 2 mg and 4 mg lozenges are referred to as NiQuitin Mint.

What is in this leaflet:

1. What NiQuitin Mint are and what they are used for
2. What you need to know before you use NiQuitin Mint
3. How to use NiQuitin Mint
4. Possible side effects
5. How to store NiQuitin Mint
6. Contents of the pack and other information

1. What NiQuitin Mint are and what they are used for

NiQuitin Mint is used to help people stop smoking. This type of treatment is called Nicotine Replacement Therapy or NRT.

NiQuitin Mint lozenges are available in two strengths. The 2 mg is intended for those who smoke the first cigarette of the day later than 30 minutes after waking. The 4 mg is intended for those who smoke the first cigarette of the day within 30 minutes after waking.

It is the nicotine in cigarettes that can make you physically addicted to them.

- NiQuitin Mint helps you to give up smoking by replacing some of the nicotine you get from cigarettes.
- This nicotine relieves some of the unpleasant symptoms that smokers may have when they try to give up. These include feeling ill or irritable.
- The nicotine can also relieve your cravings for a cigarette and help you to resist the urge to smoke.

NiQuitin Mint lozenges do not have the health dangers of tobacco. This is because they do not contain the tar, carbon monoxide or other toxins in cigarette smoke. Some people worry that after stopping smoking, they may become dependent on nicotine lozenges instead. This is very rare, and if it did happen, it is less harmful than continuing to smoke. It is also an easier habit to break.

Your chances of stopping smoking will be improved if you take part in a support programme. These “stop smoking programmes” are known as behavioural support. For information on stop smoking programmes please talk to a healthcare professional or pharmacist.

There are no health benefits to smoking. It is always better to give up smoking. Using Nicotine Replacement Therapy (NRT), like NiQuitin Mint, can help. In general, any possible side effects associated with NRT are far outweighed by the well known dangers of continuing to smoke.

2. What you need to know before you use NiQuitin Mint

Do not use NiQuitin Mint:

- if you are allergic to nicotine or any of the other ingredients of this medicine (listed in section 6)
- if you are a non-smoker or a child under 12 years of age.
- if you have phenylketonuria (PKU). NiQuitin Mint contains aspartam which is turned into phenylalanine.

NiQuitin Mint should only be used by adolescents (aged 12-17 years) if recommended by a physician.

Warnings and precautions**Talk to your healthcare professional before using NiQuitin Mint:**

- if you have high blood pressure which is not being controlled by medicines.
- if you have any cardiovascular disease, for example angina pectoris or heart failure.
- if you have cerebrovascular disease (conditions of impaired blood flow in the brain).
- if you are in hospital because of a heart attack, heart rhythm problems or a stroke. Tell the doctor that you are taking NiQuitin Mint.
- if you have inflammation in the mouth, throat or esophagus, or gastritis or peptic ulcer. Swallowing nicotine may worsen those symptoms.
- if you have liver or kidney problems because you may be more likely to get side effects.
- if you have an uncontrolled and overactive thyroid gland or have been diagnosed with a tumour of the adrenal gland (pheochromocytoma).
- if you have diabetes, the doctor may tell you to monitor your blood sugar levels more often than usual when you start using NiQuitin. Your insulin or medicine requirements may change.
- if you have ever experienced seizures.

Do not interchange between NiQuitin Mint Lozenges and nicotine gums during any attempt to quit smoking.

Some people worry that after stopping smoking, they may become dependent on nicotine replacement therapy instead. This is unusual, and if it did happen, it is less harmful than continuing to smoke. It is also an easier habit to break.

Children (under 12 years)

The correct dose for adults could seriously poison or be fatal to small children. It is therefore essential that you keep NiQuitin Mint out of sight and reach of children at all times.

Other medicines and NiQuitin Mint

Tell your healthcare professional if you are using or have recently used or might use any other medicines. This is especially important if you use other medicines like: asthma medicine (theophylline, salbutamol), medicines for depression (imipramine, clomipramine), analgesics (caffeine, pentazocine, phenacetin), anti-inflammatory agents (phenylbutazone), medicine for regulation of blood pressure (prazosin, propranolol), agents for dementia (Alzheimer's disease) (tacrine) or anti-diabetics (insulin) and medicines for irregular or fast heart beats (adenosine).

Stopping smoking may alter the effect of other medicines you may be taking. If you have any questions or concerns about this talk to your healthcare professional.

NiQuitin Mint with food or drink

You should not eat or drink while NiQuitin Mint are in your mouth. You should avoid acidic drinks such as coffee, juice and soft drinks for up to 15 minutes before you take a lozenge, as these may reduce the amount of nicotine absorbed in the mouth.

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Smoking during pregnancy has risks for the baby. These include poor growth before birth, premature birth or stillbirth. Stopping smoking is the best way to improve both your health and that of your baby. The earlier you stop smoking the better.

Ideally, if you are pregnant, you should stop smoking without using NRT. However, if you have tried and this has not worked, NRT may be recommended by a healthcare professional to help you stop smoking. This is because it is better for your developing baby than if you carry on smoking. The decision to use NRT should be made as early on as possible in your pregnancy. You should aim to use it for only 2-3 months. Remember, the most important thing is to stop smoking. Products such as lozenges may be preferable to nicotine patches. This is because with lozenges, you do not get the nicotine all the time. However, patches may be preferred if you have nausea or sickness.

Nicotine from smoking and NRT is found in breast milk. Ideally you should stop smoking without using NRT. However if you have tried and this has not worked, NRT may be recommended by a healthcare professional. If you do use NRT to help you quit, the amount of nicotine your baby may get is small. It is much less harmful than breathing in second hand smoke. It is best to use NRT products that are taken at certain times of the day (such as gum or lozenge, rather than patches). It is also better to take the product just after breast-feeding. This helps your baby to get the smallest amount of nicotine possible.

Driving and using machines

There are no known effects of NiQuitin Mint on your ability to drive or use machines. However you should be aware that giving up smoking can cause behavioural changes that could affect your ability to drive or use machines.

NiQuitin Mint contains aspartame, sodium and mannitol:

Aspartame: This medicine contains 6.1 mg aspartame in each lozenge. Aspartame is a source of phenylalanine. It may be harmful if you have phenylketonuria (PKU), a rare genetic disorder in which phenylalanine builds up because the body cannot remove it properly.

Sodium: This medicinal product contains less than 1 mmol sodium (23 mg) per lozenge, that is to say essentially sodium free.

Mannitol: May have a mild laxative effect.

3. How to use NiQuitin Mint

Always use this medicine exactly as described in this leaflet or as your healthcare professional has told you. Check with your healthcare professional if you are not sure.

Adults (18 years and over):

NiQuitin Mint lozenges are available in two strengths. The 2 mg is intended for those who smoke the first cigarette of the day later than 30 minutes after waking. The 4 mg is intended for those who smoke the first cigarette of the day within 30 minutes after waking.

Step 1 Weeks 1 to 6	Step 2 Weeks 7 to 9	Step 3 Weeks 10-12	To help stay smoke free over the next 12 weeks: use 1 to 2 lozenges per
Initial treatment period	Step down period	Step down period	

1 lozenge every 1 to 2 hours	1 lozenge every 2 to 4 hours	1 lozenge every 4 to 8 hours	day only on occasions when strongly tempted to smoke.
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Use at least 9 lozenges per day in the initial treatment period (week 1-6).

Do not use more than 15 lozenges a day.

NiQuitin Mint should not be used for more than 24 weeks (6 months). If you feel the need to use NiQuitin Mint for longer than 6 months in total, you should ask a healthcare professional for advice.

You should use NiQuitin Mint by putting one lozenge in your mouth and from time to time move it from one side of your mouth to the other, until it is completely dissolved. This should take around 20-30 minutes. Do not chew the lozenge or swallow it whole.

This product is for oromucosal use. That means that the nicotine in the lozenge is released slowly into the mouth from where it is absorbed into the body.

Use in children and adolescents

Adolescents (12-17 years inclusive)

You should only use NiQuitin Mint following advice from a doctor.

Children under 12 years

Children under 12 years of age must not use NiQuitin Mint

If you are worried that you may start smoking again

If you are worried that you may start smoking again or finding it difficult to stop using the lozenges completely, talk to a healthcare professional. If you do start to smoke again, they can advise you on how to get the best results from further courses of NRT.

If you use more NiQuitin Mint than you should

If you use too many NiQuitin Mint you may start to feel sick, dizzy and unwell. Stop using the lozenges and get advice straightaway from a doctor or hospital casualty department. If possible, show them the packet or this leaflet.

The lozenges are not suitable for children under 12 or non-smokers. If the lozenges are used by children or non-smokers they may show signs of nicotine overdose. These include headache, sickness, stomach pains and diarrhoea. If a child has used or eaten any of the lozenges, contact your doctor or nearest hospital casualty department straightaway. If possible show them the packet or this leaflet.

If you have any further questions on the use of this product, ask your healthcare professional

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. At the recommended doses NiQuitin Mint have not been found to cause any serious side effects.

Stopping smoking itself can cause symptoms such as dizziness, headache, cough and cold-like symptoms. Symptoms such as depression, irritability, anxiety and insomnia may also be related to withdrawal symptoms associated with giving up smoking.

Stop taking NiQuitin Mint and see a doctor immediately if you experience any of the following symptoms:

Uncommon: may affect up to 1 in 100 people

- Palpitations, an abnormal or fast heart beat

Very rare side effects: may affect up to 1 in 10,000 people

- Severe allergic reaction, symptoms of which include sudden wheeziness or tightness of the chest, rash and feeling faint

Not known: frequency cannot be estimated from the available data

- Seizure
- Angioedema (swollen face, tongue or throat, difficulty to swallow, hives and difficulties breathing)

Other side effects are listed below - they are based on the likelihood with which they can occur.

Very common: may affect more than 1 in 10 people

- You may feel sick
- Dizziness

Common: may affect up to 1 in 10 people

- Sore or swollen throat
- Being sick
- Stomach discomfort
- Diarrhoea
- Indigestion/heartburn
- Flatulence
- Hiccups
- Constipation
- Dry mouth
- Insomnia
- Cough
- Inflammation in the mouth
- Oral discomfort
- Headache

Uncommon: may affect up to 1 in 100 people

- Shortness of breath
- Difficulty swallowing
- Belching
- Increased sweating
- hives
- Redness of the skin

Rare: may affect up to 1 in 1000 people

- Hypersensitivity

Not known: frequency cannot be estimated from the available data

- Taste disturbance/distortion
- Numbness or tingling in the mouth
- Belching
- Increased salivation
- Abnormal dreams
- Itching or skin rash
- A fast and irregular heartbeat (atrial fibrillation)

If you get any side effects, talk to your healthcare professional. This includes any possible side effects not listed in this leaflet.

Reporting of side effects

If you get any side effects, talk to pharmacist, nurse or smoking cessation advisor . This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system to be completed nationally. By reporting side effects you can help provide more information on the safety of this medicine

5. How to store NiQuitin Mint

- **Keep this medicine out of the sight and reach of children.**
- Do not store above 25°C. Store in the original container in order to protect the product from moisture.
- Do not use the medicine after the expiry date which is stated on the container and outer packaging. The expiry date refers to the last day of the month.
- Do not use the container for anything else due to possible fine coating of tablet dust in the container.
- Do not throw 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.

6. Contents of the pack and other information

What NiQuitin Mint contain:

- The active substance is nicotine. Each lozenge contains 2 or 4 mg of nicotine (in the form of resin complex called nicotine resinate)
- The other ingredients are mannitol (E421), sodium alginate (E401), xanthan gum (E415), potassium hydrogen carbonate (E501), sodium carbonate anhydrous , aspartame (E951), magnesium stearate (E470b) and peppermint flavour (contains maltodextrin and modified starch).

What NiQuitin Mint look like and contents of the pack:

Cream/white biconvex, round compressed lozenges.

The 2 mg lozenge has a “NL2” on one side.

The 4 mg lozenge has a “NL4” on one side.

Packs contain 12, 24, 36 or 72 lozenges (blister pack). Not all pack sizes may be marketed

Marketing Authorisation Holder and Manufacturer

<[To be completed nationally]>

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

Netherlands	NiQuitin Pepermunt 2 mg / 4 mg zuigtabletten
Sweden	NiQuitin Mint 2 mg / 4 mg sugtablett

This leaflet was last revised in 2025-11-06

<[To be completed nationally]>