

1. What NiQuitin Mint 2mg and 4mg Lozenges are and what they are used for

NiQuitin Mint 2mg and 4mg Lozenges are used to help people stop smoking. This type of treatment is called Nicotine Replacement Therapy (NRT).

NiQuitin Mint 2mg and 4mg Lozenges can reduce your urge to smoke by providing some of the nicotine previously inhaled from cigarettes and helps you resist cigarettes.

NiQuitin Mint 2mg and 4mg Lozenges do not have the health dangers of tobacco because they do not contain the tar or carbon monoxide of cigarette smoke.

2. What you need to know before you take NiQuitin Mint 2mg and 4mg Lozenges

Do not take this medicine if you:

- are **allergic** to nicotine or any of the other ingredients (listed in section 6)
- are a non-smoker
- are under 12 years of age,
- suffer from phenylketonuria, a rare inherited metabolic disorder
- are allergic to soya or peanut, because this product contains soya oil

Warnings and precautions

Talk to your doctor, pharmacist or nurse before using NiQuitin Mint 2mg and 4mg Lozenges if you:

- have **heart or circulation** problems including **heart failure or stable angina** (episodes of chest discomfort that are usually predictable)
- have a recent **myocardial infarction, unstable or worsening angina pectoris** including Prinzmetal angina or a recent cardiovascular accident. You are encouraged to stop smoking without any nicotine replacement therapy (NRT) unless your doctor tells you to use them.
- have **high blood pressure**
- have occlusive **peripheral artery disease** which is a narrowing of the blood vessels outside of your heart
- have moderate to **serious liver or kidney** problems because you may be more likely to get side effects

3. How to take NiQuitin Mint 2mg and 4mg Lozenges

Important: NiQuitin Mint 4mg Lozenges are suitable for smokers who smoke within 30 minutes of waking; NiQuitin Mint 2mg Lozenges are suitable for smokers who smoke within 15 minutes of waking. NiQuitin Mint 2mg Lozenges are suitable for smokers who smoke within 30 minutes of waking. NiQuitin Mint 4mg Lozenges are suitable for smokers who smoke within 30 minutes after waking up.

Always use Nicotine Lozenges exactly as described in this leaflet. Check with your pharmacist if you are not sure.

The 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. In all cases you should use NiQuitin Mint Lozenges by putting one lozenge in your mouth and from time to time move it from one side of the mouth to the other, until it is completely dissolved. This should take around 20-30 minutes.

4. Possible side effects

Like all medicines, this medicine can cause side effects although not everybody gets them. They are similar to those you might get from the more common ways of using nicotine replacement therapy (NRT). Stopping smoking itself can cause symptoms such as dizziness, headache, sleep disturbance, cough and cold-like symptoms, depression, irritability, anxiety and night-time awakening.

Stop taking the lozenges immediately and see a healthcare professional if you get these symptoms:

- Uncommon may affect up to 1 in 100 people:
 - tachycardia (heart beating too fast)
 - peptic (stomach) ulcer, belching, abdominal pain, vomiting, loss of appetite,
 - dysphagia (difficulty swallowing)
- Very rare may affect up to 1 in 10,000 people:
 - anaphylactic reactions (severe allergic reaction or symptoms which include sudden wheeziness or tightness of the chest, rash and feeling faint).

Other side effects are listed below - they are based on the likelihood with which they can occur. You should only use *NiQuitin Mint Lozenges* following advice from a healthcare professional. **Children under 12 years of age should not use NiQuitin Mint Lozenges.**

Information: You are more likely to quit smoking when using this product, a trained counsellor, or a doctor, with help from your pharmacist, support programme.

Lozenges than you should use:

- You take more than the recommended number of lozenges per day, you may suffer a nicotine overdose and need to get advice from your doctor. Signs of overdose include headache, sickness, stomach pains and diarrhoea.
- In the event that a child has taken any lozenges or accidental overdoses occur, contact your doctor or nearest casualty department immediately as this could be fatal. If possible show them the pack or this leaflet.

If you forget to take NiQuitin Mint 2mg and 4mg Lozenges

- Do not take a double dose to make up for a forgotten dose.

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5. How to store NiQuitin Mint 2mg and 4mg Lozenges

Do not use this medicine after the expiry date printed on the pack. Do not store above 25°C and keep in the original carton.

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. Contents of the pack and other information

The active ingredient is nicotine. Each lozenge contains 2 mg or 4 mg (in the form of a resin complex called nicotine resin).

The other ingredients are: mannitol (E421), magnesium stearate, sodium alginate, xanthan gum, potassium bicarbonate, sodium carbonate anhydrous, aspartame (E951) and peppermint flavour.

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

- hypersensitivity
- Not known frequency cannot be estimated from the available data.
- It is possible that skin or mucous membrane, face, swelling and throat causing breathing difficulties

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

Reporting of suspected adverse reactions

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/ycf/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. How to store NiQuitin Mint 2mg and 4mg Lozenges

Keep all medicines out of the sight and reach of children.

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7. What this medicine contains

- erythema (skin redness), itching, rash,
- taste, taste perversion
- urticaria (hives)
- localised skin reaction, increased sweating, jaw pain
- nocturia (needing to urinate during the night)
- fluid in the legs
- overdose effect, pain, leg pain, build-up of

What your medicine looks like and contents of the pack:

Your lozenges are available in pack sizes of 12, 24, 36, 72, 132, 144 and 204's. Not all pack sizes may be marketed.

Marking Authorisation Holder

Omega Pharma Limited, 32 Vauxhall Bridge Road, London, SW1V 2SA, UK.

Manufacturer(s)

Watson Laboratories Limited, Watton Brauton, Devon, EX33 2DL, United Kingdom

Omega Pharma International NV, Venecoweg 26, Nezareth, 9810, Belgium

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PACKAGE LEAFLET: INFORMATION FOR THE USER

NiQuitin Mint 2 mg and 4mg Lozenges

Nicotine

8. What you need to know before you start using this medicine because it contains important information for you.

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

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- You must talk to a doctor if you do not feel better or if you feel worse after 6 months
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

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9. How to take NiQuitin Mint 2mg and 4mg Lozenges with food and drink

Do not eat or drink while a lozenge is in the mouth, avoid liquids which lower the pH in the mouth such as coffee, juices and soft drinks, for 15 minutes before the lozenge is used.

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