

NiQuitin Mint 2 mg & 4 mg Lozenges

Nicotine

PATIENT INFORMATION LEAFLET

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

This medicine is available without prescription. However, you still need to use *NiQuitin Mint 2mg and 4mg Lozenges* carefully to get the best results from them.

- 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 or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

IN THIS LEAFLET:

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

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.

This medicine contains:

- **nicotine resin** which when sucked, nicotine is released slowly from the resin and absorbed through the lining of the mouth. This nicotine relieves some of the cravings and unpleasant withdrawal symptoms, such as feeling ill or irritable, that smokers frequently feel when they try to give up.

If possible, when giving up smoking these lozenges should be used with a stop smoking behavioural support programme. For further information talk to your healthcare professional.

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
- have recently suffered from a heart attack, severe heart rhythm disturbances or a stroke
- have unstable or worsening angina or Prinzmetals angina

Warnings and precautions

Talk to your doctor or 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 **high blood pressure**
- have occlusive **peripheral artery disease** - which is a narrowing of the blood vessels outside of your heart
- have **serious liver or kidney** disease
- have a **stomach ulcer**
- have **inflammation of the oesophagus** (oesophagitis), which is the tube leading from the mouth to the stomach
- have an uncontrolled, **over active thyroid gland**

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 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.

If you feel the need to use *NiQuitin Mint Lozenges* for longer than 6 months in total, you should ask a healthcare professional for advice.

Do not exceed the stated dose. Follow the instructions carefully and do not use more than 15 lozenges in one day (24 hours).

Adults (aged 18 years and over):

The recommended treatment schedule is:

STEP 1	STEP 2	STEP 3
Weeks 1 to 6	Weeks 7 to 9	Weeks 10 to 12
Initial treatment period	Step down treatment period	Step down treatment period
1 lozenge every 1 to 2 hours	1 lozenge every 2 to 4 hours	1 lozenge every 4 to 8 hours

During weeks 1-6 it is recommended that you take at least 9 lozenges per day. After you have given up you may sometimes feel a sudden craving for a cigarette. You can use a lozenge again if this happens.

Adolescents (aged 12-17 years inclusive): 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*.

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

If you use more *NiQuitin Mint 2mg and 4mg Lozenges* than you should

If 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 if an accidental overdose occurs, contact your doctor or nearest hospital 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.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

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 nicotine in cigarettes, and are more likely the more nicotine you take.

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 tell 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 symptoms which include sudden wheeziness or tightness of the chest, rash and feeling faint).

Other side effects

Very common may affect more than 1 in 10 people:

- nausea

Common (may affect up to 1 in 10 people)

- insomnia (difficulty sleeping), anxiety, irritability, increased appetite
- headache
- pharyngitis (sore throat)
- vomiting, heartburn, indigestion, hiccup, mouth irritation, mouth ulceration, tongue ulceration, diarrhoea, belching, flatulence (wind)

Possible side effects continues overleaf.

- are **diabetic**, as diabetic patients need to monitor blood sugar levels more closely as nicotine from smoking or from taking these lozenges may vary them more than usual
- have been diagnosed as having a **tumour of the adrenal glands** (phaeochromocytoma)
- have had **allergic reactions** (see also section 4 "Possible side effects").

Other important information:

When you stop smoking your metabolism slows down and this may alter the way your body responds to certain medicines.

Other medicines and *NiQuitin Mint 2mg and 4mg Lozenges*

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Children and adolescents

NiQuitin Mint 2mg and 4mg Lozenges is NOT for use in children and adolescents under 12 years of age.

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 up to 15 minutes before the lozenge is used.

Pregnancy and breast-feeding

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.

If you are pregnant or breast-feeding it is best if you can give up smoking without the use of NRT. However, if you have tried and this has not worked, NRT may be recommended by a healthcare professional to help you stop smoking.

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.

The decision to use NRT should be made as early on in your pregnancy as possible. Aim to use NRT for only 2 to 3 months.

If you are breast-feeding tobacco smoke causes breathing difficulties and other problems in babies and children. If you need to use NRT, the amount of nicotine your baby may get is smaller and less harmful than breathing in second-hand smoke. It is better to breastfeed just before you take the product – this helps your baby to get the smallest amount of nicotine possible.

Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines

There are no known effects of these lozenges on your ability to drive or use machines. However, you should be aware that giving up smoking can cause behavioural changes that could affect you in this way.

NiQuitin Mint 2mg and 4mg Lozenges contains aspartame, mannitol and sodium.

Each lozenge contains about **15 mg of sodium** and the maximum daily dose of these lozenges (15 lozenges) contains 225 mg sodium. To be taken into consideration if you are on a controlled sodium diet.

Contains **aspartame (E951)** which is a source of phenylalanine. May be harmful for people with phenylketonuria.

Mannitol (E421): May cause Laxative effects.

Your lozenges are **sugar free**.

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 have their first cigarette of the day more than 30 minutes after waking up.

Always use *NiQuitin Mint Lozenges* exactly as stated 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.

Uncommon may affect up to 1 in 100 people:

- gingival bleeding (bleeding gums), nosebleed
- anger, aggravated anxiety, abnormal dreaming, abnormal hunger, mood swings, wakefulness
- lightheaded feeling, localised numbness
- palpitations (feeling your heartbeat)
- vascular disorder, flushing
- laryngismus (throat spasms), aggravated asthma, lower respiratory tract infection, coughing, nasal irritation, throat irritation, nasal congestion
- peptic ulcer, gastroesophageal reflux, hiatus hernia, oesophagitis (inflammation of the oesophagus), borborygmus (rumbling stomach), dry lips, dry throat, tongue disorder, tooth ache
- parageusia (bad taste in the mouth), metallic taste, taste perversion
- erythema (skin redness), itching, rash, localised skin reaction, increased sweating
- jaw pain
- nocturia (needing to urinate during the night)
- overdose effect, pain, leg pain, build-up of fluid in the legs

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

Reporting of side effects:

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 the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard. 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.

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

What this medicine contains

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

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

What your medicine looks like and contents of the pack:

Cream / white circular compressed lozenge with an odour of peppermint.

The 2 mg lozenge is embossed with L344 on one side.

The 4 mg lozenge is embossed with L873 on one side.

Your lozenges are available in pack sizes of 36 and 72's. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Wrafton Laboratories Limited, Wrafton, Braunton, Devon, EX33 2DL, United Kingdom

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