

PACKAGE LEAFLET : INFORMATION FOR THE USER

NiQuitin 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 describes in this leaflet or as your healthcare professional has 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.
- Throughout this leaflet NiQuitin 4 mg Lozenges are referred to as NiQuitin.

In this leaflet:

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

1. What NiQuitin are and what they are used for

NiQuitin are used to help people stop smoking. This type of treatment is called Nicotine Replacement Therapy or NRT. NiQuitin 4 mg Lozenges are suitable for smokers who smoke 20 cigarettes or more a day.

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

- NiQuitin help 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 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 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.

There are no health benefits to smoking. It is always better to give up smoking. Using Nicotine Replacement Therapy (NRT), like NiQuitin, 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 take NiQuitin

Do not use NiQuitin if:

- you are allergic (hypersensitive) to nicotine or any of the other ingredients in this medicine (listed in Section 6:)
- you are a non-smoker or under the age of 12 years.

Warning and precautions

Talk to your healthcare professional before using NiQuitin:

- **If you have had a recent heart attack or stroke, or you suffer from severe heart rhythm problems, unstable or worsening angina (chest pain) or resting angina** you should try to quit smoking without using any NRT products unless your doctor tells you to use them.
- **If you have diabetes** you should monitor your blood sugar levels more often than usual when you start using NiQuitin. Your insulin or medicine requirements may change.
- If you have a history of epilepsy (fits)
- **If you have ever had allergic reactions** that involve swelling of the lips, face and throat (angioedema) or itchy skin rash (urticaria). Using NRT can sometimes trigger this type of reaction.

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

Get help and advice from a healthcare professional if you have:

- **Severe or moderate liver or severe kidney problems** because you may be more likely to get side effects.
- **Uncontrolled overactive thyroid gland or pheochromocytoma** (a tumour of the adrenal gland that can affect blood pressure) - your doctor will have told you this - because nicotine may make your symptoms worse.
- **Stomach or duodenal ulcers or an inflamed oesophagus or gullet** (the passage between the mouth and stomach) because swallowing nicotine can make your symptoms worse. It may also cause mouth ulcers. If your symptoms do get worse you should talk to your doctor. You might want to use a non-oral form of NRT instead, such as patches.
- Any concerns about becoming dependent or think you have become dependent on this product.

Children and adolescents

This medicinal product must not be used by children under the age of 12 years. A normal dose for an adult smoker could seriously poison or even cause death to children. It is therefore essential to keep NiQuitin out of the sight and reach of children at all times.

Other Medicines and NiQuitin Please tell your healthcare professional if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

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.

Pregnancy and breast feeding

If you are pregnant or breast-feeding, think you may be pregnant or planning to baby ask your doctor 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.

If you are **breast feeding** tobacco smoke causes breathing difficulties and other problems in babies and children. 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 breast feed just before you take the product. This helps your baby to get the smallest amount of nicotine possible.

Driving and using machines

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

NiQuitin contain

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

3. How to use NiQuitin

Always use NiQuitin exactly as stated in this package leaflet. You should check with your healthcare professional if you are not sure.

You should use NiQuitin 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 10 minutes. Do not chew the lozenge or swallow it whole. Do not use more than 15 lozenges a day. If you feel the need to use NiQuitin for longer than 9 months in total, you should ask a healthcare professional for advice.

Adults (18 years and over)

- Start by using 8 to 12 lozenges a day. Suck a lozenge whenever you have an urge to smoke.
- Use the lozenges like this for up to 6 weeks, then gradually cut down the number of lozenges you use a day.
- Once you are using only 1 or 2 lozenges a day, stop using them altogether.

After you have given up you may sometimes feel a sudden craving for a cigarette. You can use a lozenge again if this happens.

Use in children and adolescents

Young people (12-17 years inclusive)

You should only use NiQuitin following advice from a healthcare professional.

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

Children under 12 years of age must not use NiQuitin.

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

If you are tempted to start smoking again

If you are worried that you may start smoking again or are 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 Nicotine Replacement Therapy (NRT).

If you take more NiQuitin than you should

If you use too many NiQuitin 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 NiQuitin can cause side effects, although not everybody gets them. At the recommended doses NiQuitin have not been found to cause any serious side effects.

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

Other Side effects are listed below - they are grouped based on the likelihood with which they can occur:

Very common (may affect *more than* 1 in 10 people)

- The lozenges may cause your mouth or tongue to be slightly sore or irritated. You may also feel sick.

Common (may affect *up to* 1 in 10 people)

- Sore throat
- Being sick
- Stomach discomfort
- Diarrhoea
- Indigestion/heartburn
- Flatulence
- Hiccups
- Pharyngitis

Uncommon side effects (may affect *up to* 1 in 100 people)

- Nervousness
- Depression
- Palpitations (feeling your heart beat)
- Increased heart beat
- Chest pain
- Rash
- Tiredness and generally feeling unwell

Very rare (may affect 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)

- Seizures (fits)
- Dysphagia (difficulty to swallow)
- Eructation (a reflex that expels gas noisily from the stomach through the mouth belch)
- Increased salivation
- Influenza like illness (flu like symptoms)

- Hypersensitivity
- Tremor, Dysgeusia (taste perversion), paresthesia mouth (numbness or tingling in the mouth)
- Dyspnoea (shortness of breath)
- Itching or a rash, swelling of skin or mucous membrane, redness of the skin, increased sweating
- A fast and irregular heartbeat (atrial fibrillation)

Reporting of side effects

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. You can also report side effects directly via the national reporting system listed in Appendix V.* By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store NiQuitin

- **Keep all medicines out of the sight and reach of children.**
- Do not use the lozenges after the expiry date stated on the container and outer packaging. The expiry date refers to the last day of the month.
- Do not store above 25°C.
- Store in the original container in order to protect from moisture.
- Do not use the container for anything else due to possible fine coating of tablet dust in the container.
- Dispose of the container responsibly. 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. Content of the Pack and Other Information

What NiQuitin contain

The active substance is nicotine. Each lozenge contains 4 mg (in the form of a resin complex called nicotine resinate). **The other ingredients** are mannitol (E421), sodium alginate (E401), xanthan gum (E415), potassium bicarbonate (E501), calcium polycarbophil, sodium carbonate anhydrous (E500), acesulfame potassium (E950), mint flavor powder, sucralose (E955), magnesium stearate (E470b).

What NiQuitin look like and contents of the pack

White to off-white oval compressed lozenges (lozenges) with convex surfaces. The 4 mg lozenge has an “NIC4” on one side.

Each container contains 20 lozenges. Packs may contain one, three or five containers.

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:

To be completed nationally.

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