

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 described 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.

Throughout this leaflet NiQuitin 4 mg Lozenges are referred to as NiQuitin Lozenges.

What is in this leaflet:

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

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

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

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

NiQuitin Lozenges 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 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 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 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 use NiQuitin Lozenges

Do not use NiQuitin Lozenges:

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 under the age of 12 years.

Warnings and precautions

Talk to your healthcare professional before using NiQuitin Lozenges:

- 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 Lozenges. Your insulin or medicine requirements may change.
- 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.
- if you have a history of epilepsy (fits).
- if you have children under 12 years as the levels of nicotine in NRT are not suitable for children under 12.

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

If you are pregnant or breast feeding it is best if you can give up smoking without the use of NRT. However, it is better to stop smoking using NRT than to continue smoking. (See the section on pregnancy and breastfeeding below for more information.)

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

- serious liver or 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.
- any concerns about becoming dependent or think you have become dependent on this product
- 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 nicotine patches.

Children (under 12 years)

Do not give this medicine to children under the age of 12 years because it could cause severe poisoning in children and cause death.

Other medicines and NiQuitin Lozenges

Tell your healthcare professional if you are using or have recently used or might use any other medicines.

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

Pregnancy and breast-feeding

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 need to 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 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 your ability to drive or use machines.

NiQuitin Lozenges contain:

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

Aspartame - A source of phenylalanine. May be harmful to you if you suffer from phenylketonuria.

Mannitol - NiQuitin Lozenges may have a mild laxative effect.

3. How to use NiQuitin Lozenges

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.

During any attempt to give up smoking using NiQuitin Lozenges it is important that you make every effort to stop smoking completely. However, if you do smoke a cigarette while you are using NRT, you should continue your quit attempt. If you continue to have difficulty stopping smoking talking to your doctor, nurse, smoking cessation advisor or pharmacist may help.

You should use NiQuitin Lozenges by putting one lozenge in your mouth and periodically move it from one side of your mouth to the other, until it's completely dissolved. This should take 20 to 30 minutes. Do not chew the lozenge or swallow it whole. You should not eat or drink while a lozenge is in your mouth as this may reduce the absorption of the nicotine.

Do not use more than 15 lozenges a day. If you feel the need to use NiQuitin Lozenges for longer than 9 months in total, you should ask a healthcare professional for advice.

Adults (18 years and over)

NiQuitin 4 mg Lozenges are for smokers who have their first cigarette of the day within 30 minutes of waking up.

For the first 6 weeks use at least 9 lozenges a day

To help you stay smoke free over the next 12 weeks, you can take 1-2 lozenges per day in situations where you are strongly tempted to smoke.

Once you are using only 1-2 lozenges a day, stop using them altogether.

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

Do not exceed the stated dose.

Use in children and adolescents

Adolescents (12-17 years inclusive)

You should follow the instruction above for stopping smoking straightaway but you should only use the lozenges for 12 weeks in total. If you feel the need to use NiQuitin Lozenges for longer than 12 weeks or if you are not ready to stop smoking straightaway, you should talk to 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).

Children under 12 years

Children under 12 years of age should not use NiQuitin Lozenges.

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

Talk to a healthcare professional if you are:

- worried that you may start smoking again
- finding it difficult to stop using the lozenges completely

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 Lozenges than you should

If you use too many NiQuitin Lozenges 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 Lozenges have not been found to cause any serious side effects.

Stop using this medicine and seek medical attention immediately if you have the following symptoms:

- Allergic reactions, tremor, angioedema (swelling of skin or mucous membrane, face, tongue and throat causing breathing difficulties), dyspnoea (shortness of breath)

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

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 feeling sick

Common: may affect up to 1 in 10 people
sore throat, mouth/tongue irritation or ulceration dry mouth, difficulty swallowing being sick,
bloating, constipation diarrhoea, indigestion, heartburn, flatulence, dry mouth, constipation,
pharyngitis (swelling in the back of the throat) , hiccups, coughing, headache, dizziness

None of the above effects are serious and often wear off after a few days treatment.

Uncommon: may affect up to between 1 in 100 people
sensory disturbance, breathing problems, catarrh, shortness of breath
stomach cramps, acid regurgitation
nightmares, migraine, restlessness, change in appetite
lethargy, feeling unwell, chest pain or tightness
taste disturbance, mouth numbness, bleeding gums, bad breath, increased salivation
rash, itching hot flushes.

Very rare: 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)
Seizures (fits), increased salivation, asthenia (lack of energy), fatigue (tiredness), malaise (feeling
of general discomfort), influenza like illness (flu like symptoms)

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 HPRA Pharmacovigilance, Earlsfort Terrace, IRL – Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie.

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

5. How to store NiQuitin Lozenges

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the blister and carton. The expiry date refers to the last day of that month. The expiry date refers to the last day of that month.

Do not store above 25°C.

Store in the original package.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What NiQuitin Lozenges contain

The active substance is nicotine 4 mg (in the form of nicotine resinate).

The other ingredients are mannitol (E421), sodium alginate (E401), xanthan gum (E415), potassium hydrogen carbonate (E501), polycarbophil calcium, anhydrous sodium carbonate (E500i), aspartame (E951), magnesium stearate (E470b) and menthol mint flavour (menthol, peppermint oil, maltodextrin, colloidal anhydrous silica).

What NiQuitin Lozenges look like and contents of the pack

White, round compressed lozenges with convex surfaces.

NiQuitin Lozenges have “NL4” on one side.

Blister packs contain 12, 36 or 72 lozenges.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Chefaro Ireland DAC, The Sharp Building, Hogan Place, Dublin 2, Ireland

Famar A.V.E ANTHOUSSA PLANT, Anthoussa Avenue 7, Anthoussa Attiki, 15344 Greece

This medicinal product is authorized in the Member States of the EEA under the following names:

Belgium, Luxembourg – NiQuitin Lozenge 4mg

Ireland – NiQuitin 4mg Lozenge

Italy – NiQuitin 4mg Pastigle

Portugal – NiQuitin 4mg Comprimidos para Chupar

United Kingdom – Nicabate 4mg Lozenge

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