

PACKAGE LEAFLET: INFORMATION FOR THE USER

NiQuitin Citrus 4 mg compressed lozenge 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. See section 4.
- You must consult a doctor if you are not able to reduce or quit smoking or use of NiQuitin Citrus. See section 3.
- Throughout this leaflet NiQuitin Citrus 4 mg compressed lozenge is referred to as NiQuitin.

What is in this leaflet:

1. What NiQuitin is and what it is 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. Content of the pack and other information

1. What NiQuitin is and what it is used for

NiQuitin are used to help people stop smoking. This type of treatment is called Nicotine Replacement Therapy or NRT. NiQuitin is indicated in adults and adolescents (12-17 years, after advice from healthcare professional).

NiQuitin are intended for smokers who smoke *more than 20 cigarettes* a day.

Permanent cessation of tobacco use is the eventual objective. NiQuitin can also be used for gradual cessation for smokers who are unwilling or unable to quit abruptly. NiQuitin should preferably be used in conjunction with a behavioral support programme. See Section 3 “How to use NiQuitin ” for further details.

- 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.

do not have the health dangers of tobacco. NiQuitin does 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 such as NiQuitin 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 support programmes. For information on these 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 dangers of smoking.

2. What you need to know before you take NiQuitin

Do not use NiQuitin if:

- you are allergic to nicotine or any of the excipients listed in section 6

- you are under the age of 12 years
- you are a non-smoker

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 pectoris (chest pain) or resting angina pectoris** you should try to quit smoking without using any NRT products unless your doctor tells you to use them.
- if you are pregnant or breastfeeding

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

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

- **heart or circulation problems** including **heart failure, stable angina, high blood pressure or occlusive peripheral artery disease**
- **diabetes** you should monitor your blood sugar levels more often than usual when you start using NiQuitin. Your insulin or medicine requirements may change.
- **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.
- **severe** or **moderate liver** or **severe kidney problems** because you may be more likely to get side effects.
- **uncontrolled overactive thyroid gland** or **phaeochromocytoma** (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.
- a history of **epilepsy** (fits).
- any concerns about becoming dependent or think you have become dependent on this product.

Children and adolescents

This medicine 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 always essential to keep NiQuitin out of the sight and reach of children. Adolescents (12-17 years) should only use NiQuitin following advice from a healthcare professional.

Other medicines and NiQuitin

Tell your healthcare professional if you are taking or have recently taken any other medicines. Nicotine may possibly enhance some effects of medicines for irregular or fast heart beats (adenosine) i.e. increase in blood pressure, heart rate and pain response.

Stopping smoking may alter the effect of other medicines you may be taking. If you have any questions or concerns, talk to a healthcare professional. The following may require adjustment in dose at cessation of smoking: asthma medicine (theophylline), analgesics (pentazocine), medicines to restore normal heart rhythm (flecainide), antipsychotics (clozapine, olanzapine), dopamine agonists (ropinirole) and caffeine.

NiQuitin with Food and Drink

You should not eat or drink while NiQuitin is in your mouth.

Drinks such as coffee, juice and soft drinks, can make nicotine less effective. These liquids should be avoided up to 15 minutes before using NiQuitin.

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.

Pregnancy

Smoking during **pregnancy** has risks for the baby including 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 quit the better.

Ideally, if you are pregnant, you should stop smoking without using NRT. If you have tried and this has not worked, NRT may be recommended by a healthcare professional. This is because it is better for your baby than if you carry on smoking.

Breast feeding

If you are **breast feeding** tobacco smoke causes breathing difficulties and other problems in babies and children. Nicotine from smoking and NRT is found in breast milk. You should try to quit first without using NRT. If you have tried and this has not worked, NRT may be recommended by a healthcare professional. If you need NRT to quit, the amount of nicotine your baby may get is small but this is still much less harmful than breathing in smoke. Oral NRT may be preferable to patches because you do not get the nicotine continuously. It is also better to breast feed just before you take NRT so that your baby gets as little nicotine as possible.

Driving and using machines

There are no known effects of NiQuitin on the ability to drive or use machines. However quitting smoking can cause behavioural changes that could affect your ability to drive or use machines.

NiQuitin contain sodium

This medicine contains less than 1 mmol sodium (23 mg) per compressed lozenge, that is to say essentially sodium free.

3. How to use NiQuitin

Always use NiQuitin Citrus exactly as stated in this package leaflet or as your healthcare professional has told you. Check with your healthcare professional if you are not sure.

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 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.

Further instructions about how to use NiQuitin depend on whether you are:

- (a) stopping smoking straightaway
- (b) cutting down before stopping

Adults (18 years and over)

(a) Stopping smoking straightaway

- Take one lozenge (using 8-12 a day) whenever you have any urge to smoke 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.

(b) Cutting down before stopping smoking

When you feel a strong urge to smoke, use a NiQuitin instead of a cigarette. Cut down the number

of cigarettes you smoke per day by as many as possible. If you have not been able to cut down the number of cigarettes you smoke each day after 6 weeks, talk to a healthcare professional. As soon as you feel able, give up cigarettes completely. Follow the instructions for “(a) Stopping smoking straightaway” above as soon as possible. If you have not stopped smoking completely within 6 months of starting NiQuitin, speak to 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)**.

If you feel the need to use NiQuitin for **longer than 9 months** in total, you should ask a healthcare professional for advice.

Use in children and adolescents

Adolescents (12-17 years inclusive)

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

Children under 12 years

Children under 12 years must **not** use NiQuitin

Talk to a healthcare professional if you are:

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

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 take more NiQuitin 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 must not be used in children under 12 or non-smokers. If 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.

4. Possible Side Effects

Like all medicines NiQuitin can cause side effects, although not everybody gets them.

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

If you notice any of the following serious side effects **stop taking NiQuitin** and **contact a doctor immediately**, as they may be a sign of severe allergic reaction:

- Severe allergic reaction, symptoms of which include sudden wheeziness or tightness of the chest, rash and feeling faint, frequency very rare
- Swelling of skin or mucous membrane, face, tongue and throat causing breathing difficulties, frequency not known

Other Side effects which may occur:

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

- Nausea, vomiting
- Sleep disturbance

Common (may affect up to 1 in 10 people)

- Nervousness, dizziness, headaches
- Diarrhea
- Tremor
- Constipation
- Indigestion/heartburn
- Flatulence
- Hiccups
- Sore throat
- Cough
- Difficulty breathing, shortness of breath
- Abdominal upper pain
- Dry mouth
- Mouth ulcers
- Oral discomfort
- Fatigue (tiredness)
- Feeling of general discomfort
- Flu like symptoms
- Lack of energy

Uncommon (may affect up to 1 in 100 people)

- Difficulty swallowing
- Palpitations (feeling your heartbeat)
- Increased heartbeat

Rare (may affect up to 1 in 1,000 people)

- Hypersensitivity

Not known (frequency cannot be estimated from the available data)

- Seizures (fits)
- Abnormal dreams, depression, irritability, anxiety, taste disturbance/distortion, rash
- Itching
- Redness of the skin
- Increased sweating
- Hives
- Tingling mouth, belching
- Salivary hypersecretion
- A fast and irregular heartbeat (atrial fibrillation)

Reporting of side effects

If you get any side effects, talk to your healthcare professional. 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 this medicine out of the sight and reach of children.
 - Do not use this medicine after the expiry date which is stated on the carton and container after EXP. The expiry date refers to the last day of that month.
- Do not store above 25°C.
- Store in the original tablet 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.
- 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. Content of the Pack and Other Information

What NiQuitin contain

Each compressed lozenge contains nicotine resinate equivalent to 4 mg nicotine.

The other ingredients are mannitol (E421), sodium alginate (E401), xanthan gum, (E415), potassium hydrogen carbonate (E 501), calcium polycarbophil, sodium carbonate (E 500), acesulfame potassium (E950), citrus flavour, magnesium stearate (E470b), sucralose.

What NiQuitin look like and contents of the pack

The lozenge size to the nearest mm is: L: 10 mm × W: 5 mm.

White to off-white oval compressed lozenges (lozenges) with convex surfaces.

The 4 mg compressed lozenge has an “CIT4” on one side.

Packs may contain 1 (including 20 lozenges in total), 3 (including 60 lozenges in total) or 5 (including 100 lozenges in total) tablet containers.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

To be completed nationally.

This medicine is authorised in the Member States of the European Economic Area under the following names:

[To be completed nationally.]

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To be completed nationally