

Package leaflet: Information for the user

NiQuitin Mini 4mg Mint 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. See section 4.
- Throughout this leaflet NiQuitin Mini 4mg Mint Lozenges are referred to as NiQuitin Minis 4mg.

What is in this leaflet

1. What NiQuitin Minis 4mg are and what they are used for
2. What you need to know before you take NiQuitin Minis 4 mg
3. How to use NiQuitin Minis 4mg
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1. What NiQuitin Minis 4mg are and what they are used for

NiQuitin Minis 4mg are used to help people stop smoking. This type of treatment is called Nicotine Replacement Therapy (or NRT for short).

This pack contains NiQuitin Minis 4mg which are for smokers who smoke *more than 20 cigarettes a day*.

They can help you give up smoking straightaway. They can also help you cut down smoking before stopping completely. If you think you can stop smoking straightaway, then you should because this is usually best. However, if you feel this is too big a step, then you may wish to try cutting down the amount of cigarettes you smoke as a first step before stopping completely. NiQuitin Minis may be used together with NiQuitin Patches if you have relapsed after trying to quit with NRT, when one NiQuitin product is not enough to control your cravings, or if you are a heavy smoker (e.g. more than 10 cigarettes per day). See Section 3 “How to use NiQuitin Minis 4mg” for further details.

It is the nicotine in cigarettes that can make you physically addicted to them. NiQuitin Minis 4mg help you to give up smoking by replacing some of the nicotine you get from cigarettes. This relieves some of the unpleasant symptoms that smokers may get when they try to quit, relieve cravings for a cigarette and help to resist the urge to smoke.

NRT does not have the health dangers of tobacco. It does not contain the tar, carbon monoxide or other toxins in cigarette smoke. Some people worry that they may become dependent on the nicotine in NRT lozenges instead. This is very rare, but if it did happen, it is less harmful than continuing to smoke. It is also an easier habit to break.

Your chances of quitting will be improved if you take part in a **support programme**. For information on these, talk to a healthcare professional. You can also call the National Smoker’s Helpline on 1800 201 203 or visit www.quit.ie.

There are no health benefits to smoking. It is always better to give up smoking. Using NRT, like NiQuitin Minis 4mg, 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 Minis 4mg

Do not use NiQuitin Minis 4mg:

- if you are allergic (hypersensitive) to nicotine or any of the other ingredients in 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 Minis 4mg:

- 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 nicotine replacement therapy (NRT) unless your doctor tells you to use it.
- if you have heart or circulation problems including heart failure, stable angina, high blood pressure or occlusive peripheral artery disease.
- if you have diabetes. You should monitor your blood sugar levels more often than usual when you start using NiQuitin Minis 4mg. Your insulin or medicine requirements may change.
- if you have a history of epilepsy, experienced seizures (fits).
- if you have ever had allergic reactions that involve swelling of the lips, face and throat or itchy skin rash. Using NRT can sometimes trigger this type of reaction.
- if you have heart problems, you should consult your doctor before using NiQuitin Minis 4mg and NiQuitin patches together.
- if you have severe or moderate liver or severe kidney problems. You may be more likely to get side effects.
- if you have uncontrolled, overactive thyroid gland or pheochromocytoma (a tumour of the adrenal gland that can affect blood pressure) - Nicotine may make symptoms worse.
- if you have stomach or duodenal ulcers or an inflamed oesophagus (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.
- if you have concerns about becoming dependent or think you have become dependent on this product.
➔ Talk to your healthcare professional before using NiQuitin Minis 4mg if any of these apply to you.

Do not interchange between NiQuitin Minis 4mg and nicotine gums during any attempt to quit smoking.

Children (under 12 years)

The levels of nicotine in NRT are not suitable for children under 12. Nicotine affects children more than adults. It could cause severe poisoning in children which can cause death. It is therefore essential to keep NiQuitin Minis 4mg out of the sight and reach of children at all times.

Other medicines and NiQuitin Minis 4mg

Tell your healthcare professional if you are taking or have recently taken 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

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.

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 nicotine replacement therapy (NRT). However, if you have tried and this has not worked, **nicotine replacement therapy may be recommended by a healthcare professional**. This is because it is better for your baby than if you carry on smoking. You should use NRT as early on as possible in your pregnancy and ideally for only 2-3 months. Remember, the most important thing is to stop smoking. Oral NRT such as lozenges may be preferable to patches, because you do not get the nicotine continuously. However, patches may be better if you have nausea or sickness.

If you are **breast feeding**, tobacco smoke causes breathing difficulties and other problems in babies and children. 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 less harmful than breathing in smoke. Products such as lozenges 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.

Do not use NiQuitin Minis 4mg in combination with NiQuitin patches if you are pregnant or breast feeding unless a healthcare professional considers it necessary. This is because this combination has not been tested in women who are pregnant or breast-feeding.

Driving and using machines

There are no known effects of NiQuitin Minis 4mg on the ability to drive or use machines. However, quitting smoking can cause behavioural changes that could affect you in this way.

NiQuitin Minis 4mg contains 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 Minis 4mg

The instructions about how to use NiQuitin Minis 4mg depend on whether you are:

- (a)** stopping smoking straightaway
- (b)** cutting down before stopping
- (c)** combining NiQuitin Minis 4mg and patches

Always use NiQuitin Minis 4mg exactly as stated in this package leaflet. You should check with your healthcare professional if you are not sure.

NiQuitin Minis 4mg are for smokers who smoke more than 20 cigarettes a day.

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

In all cases you should use NiQuitin Minis 4mg 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. When using NiQuitin Minis 4mg in combination with patches do not use more than 10 lozenges a day. If you feel the need to use NiQuitin Minis 4mg for longer than 9 months in total, you should ask a healthcare professional for advice.

(a) Stopping smoking straightaway 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 NiQuitin Mini lozenge again if this happens.

(b) Cutting down before stopping smoking

Adults (18 years and over)

When you feel a strong urge to smoke, use a NiQuitin Minis 4mg instead of a cigarette to help you manage your cravings. 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, you should give up cigarettes completely. Follow the instructions for stopping smoking straightaway given above. Do this as soon as possible. If your attempt to stop smoking completely has not been successful within 6 months of starting the use of NiQuitin Minis 4mg, speak to a healthcare professional.

(c) Combining NiQuitin Minis 4mg and patches

Adults (18 years and over)

NiQuitin Minis 4mg are not always enough on their own. **Using NiQuitin Minis at the same time as patches may help** to control sudden cravings and increase your chance of quitting than with NiQuitin Minis alone.

Combining NiQuitin Minis and NiQuitin Patches may help:

- if you have relapsed after trying to quit with NRT,
- if one NiQuitin product is not enough to control your cravings
- if you are a heavy smoker (e.g. you smoke 10 or more cigarettes per day)
- only if you are 18 years or older and any of the above apply

Follow the ‘Step’ process with the patches but take NiQuitin Minis 4 mg whenever you experience a sudden craving - around 5-6 lozenges are recommended per day. See table below for details.

When using patches and NiQuitin Minis together:

- do not take more than 15 pieces of NiQuitin Minis 1.5mg in 24 hours
- do not take more than 10 pieces of 4mg oral NiQuitin in 24 hours

For more information, read the leaflet that comes with NiQuitin patch.

Period	Patches	NiQuitin Minis
For <u>first</u> 6 weeks	Step 1, 21 mg / 24 hours patch every day	5 to 6 lozenges of NiQuitin Minis 4 mg per day
Weeks 7 and 8	Step 2, 14 mg / 24 hours patch every day	Continue to use NiQuitin Minis 1.5 mg, when necessary
Weeks 9 and 10	Step 3, 7 mg / 24 hours patch every day	
After 10 weeks	Stop using patches	Reduce the amount of NiQuitin Minis 1.5 mg gradually. When this is down to 1-2 lozenges, stop treatment.

Use in children and adolescents

Adolescents (12-17 years inclusive)

You should only use NiQuitin Minis 4mg following advice from a healthcare professional. You should not use NiQuitin Minis 4mg in combination with NiQuitin patches.

Children under 12 years must not use NiQuitin Minis 4mg.

Do not exceed the stated dose. Follow the instructions carefully and do not use more than 15 lozenges in one day (24 hours). When using NiQuitin Minis 4mg in combination with patches do not use more than 10 lozenges in one day (24 hours).

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 suggest how to get the best results from further courses of nicotine replacement therapy.

If you take more NiQuitin Minis 4mg than you should

If you use too many NiQuitin Minis 4mg 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 used by children or non-smokers they may show signs of nicotine overdose, such as 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 Minis 4mg can cause side effects, some more common than others, although it is possible you may not get any side effects at all. At the recommended doses NiQuitin Minis 4mg 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. Other symptoms may also be related to giving up smoking such as depression, irritability, anxiety, restlessness, increased appetite and insomnia.

Other Side effects are listed below - they are group 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
- constipation
- dry mouth
- mouth discomfort
- mouth ulcers

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 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)
- 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

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRC Pharmacovigilance. Website: www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store NiQuitin Minis 4mg

- **Keep 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. Contents of the pack and other information

What NiQuitin Minis 4mg contains

The active substance is nicotine 4mg (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), sucralose (E955), mint flavour powder, magnesium stearate (E470b).

NiQuitin Minis 4mg are sugar free.

What NiQuitin Minis 4mg looks like and contents of the pack

White to off-white oval lozenges with convex surfaces.

The 4mg 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

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

Manufacturer(s)

Perrigo Supply Chain International DAC, The Sharp Building, 10-12 Hogan Place, Dublin 2, Ireland
Omega Pharma International NV, Venecoweg 26, Nazareth, 9810, Belgium

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

Czech Republic & Slovakia - NiQuitin Mini 4mg;

Estonia - NiQuitin Mini 4mg Lozenges;

Hungary - NiQuitin Minitab 4mg préselt szopogató tablettá;

UK - Nicabate CQ 4mg Mint Lozenges.

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