

## 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 4mg
3. How to use NiQuitin Minis 4mg
4. Possible side effects
5. How to store NiQuitin Minis 4mg
6. Contents of the pack and other information

#### **1. What NiQuitin Minis 4mg are and what they are used for**

NiQuitin Mini 4mg are used to help people stop smoking. This type of treatment is called Nicotine Replacement Therapy or NRT.

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.

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 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 Mini 4mg 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 is 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. You can also call the National Smoker’s Helpline on 1800 201 203 or visit [www.quit.ie](http://www.quit.ie).

There are no health benefits to smoking. It is always better to give up smoking. Using Nicotine Replacement Therapy (NRT), like NiQuitin Minis 4mg, 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 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)
- 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 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 Minis 4mg. 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.
- If you have **heart problems**, you should consult your doctor before using NiQuitin Minis 4mg and NiQuitin patches together.

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

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

- **If you have heart or circulation problems including heart failure, stable angina, high blood pressure or occlusive peripheral artery disease**
- **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.
- If you have ever experienced seizures (fits).
- 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 Minis 4mg out of the sight and reach of children at all times.

### Other medicines and NiQuitin Minis 4mg

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 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. 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.

Due to an absence of specific studies, use of NiQuitin Minis 4mg in combination with NiQuitin patches is not recommended during pregnancy unless a healthcare professional considers it necessary.

If you are **breastfeeding**, 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 breastfeed just before you take the product. This helps your baby to get the smallest amount of nicotine possible.

Due to an absence of specific studies, use of NiQuitin Minis 4mg in combination with NiQuitin patches is not recommended if you are breast feeding unless a healthcare professional considers it necessary.

### **Driving and using machines**

There are no known effects of NiQuitin Minis 4mg on the ability to drive or use machines. However you should be aware that giving up smoking can cause behavioural changes that effect your ability to drive or use machines.

### **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 4 mg 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)**

In some instances (e.g. if you smoke 10 or more cigarettes per day, or you have relapsed after the use of NiQuitin before, or when one NiQuitin product is not enough to control your cravings), it may be beneficial to use NiQuitin Minis 4mg in combination with NiQuitin patches – to help control sudden cravings

If you experience strong cravings to smoke, combination therapy of transdermal patches and oral forms of nicotine such as NiQuitin Minis 4mg provide a better chance of quitting than patches alone.

The recommended dosage follows the ‘Step’ process as outlined in the table below. Take NiQuitin Minis 4 mg for 6 weeks, ‘Step 1’, whenever you experience a sudden craving - on average 5-6 lozenges are recommended per day. Do not exceed 10 lozenges of NiQuitin Minis 4 mg in 24 hours.

You should continue to use NiQuitin Minis 1.5 mg for 4 weeks, ‘Step 2 and Step 3’, beginning to reduce use gradually as you experience less nicotine cravings. When daily use is reduced to 1-2 doses, use should be stopped. Do not exceed 15 Lozenges of NiQuitin 1.5 mg in 24 hours.

<b>Period</b>	<b>Patches</b>	<b>NiQuitin Minis</b>
Step 1: <u>first</u> 6 weeks	NiQuitin 21 mg / 24 hours	5 to 6 lozenges of NiQuitin Minis 4 mg per day
Step 2: <u>next</u> 2 weeks	NiQuitin 14 mg / 24 hours	Continue to use NiQuitin Minis 1.5 mg, when necessary
Step 3: <u>last</u> 2 weeks	NiQuitin 7 mg / 24 hours	
<u>Beyond Step 3:</u> After 10 weeks	Stop using NiQuitin patches	Reduce the number of NiQuitin Minis 1.5 mg gradually. When daily use is reduced to 1-2 lozenges, treatment should be stopped.

For more information, please refer to the patient information leaflet you received with your NiQuitin patch.

### **Use in children and adolescents**

#### **Young people (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.

**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).**

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

#### **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 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 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.

## **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. 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 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRAs Pharmacovigilance. Website: [www.hpra.ie](http://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 this medicine 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):**

Wrafton Laboratories Ltd, Exeter Road, Wrafton, Braunton, EX33 2DL, United Kingdom

Omega Pharma International NV, Venecoweg 26, Nazareth, 9810, Belgium

**NiQuitin** is a registered trademark of ELAN PHARMA INTERNATIONAL LTD.

**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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