

**PACKAGE LEAFLET**

## Package leaflet: Information for the user

### NiQuitin 2 mg 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.

Throughout this leaflet NiQuitin 2 mg Mint Lozenges are referred to as NiQuitin Mint Lozenges.

#### **What is in this leaflet:**

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

#### **1. What NiQuitin Mint Lozenges are and what they are used for**

NiQuitin Mint 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 Mint 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 Mint 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. 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 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 Mint Lozenges

### Do not use NiQuitin Mint Lozenges:

- if you are allergic to nicotine or any of the other ingredients of this medicine (listed in section 6)
- if you are allergic to peanut or soya
- if you are a non-smoker or under the age of 12 years.

### Warnings and precautions

Talk to your healthcare professional before using NiQuitin Mint 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 Mint 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 Mint 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 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.
- 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.
- been told by your doctor that you have an intolerance to some sugars.

### 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 Mint 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 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 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 Mint 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 Mint Lozenges contain:**

**Sodium** - This medicinal product contains less than 1mmol (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** – Nicabate Mint Lozenges may have a mild laxative effect.

**Lactose** - If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking Nicabate Mint Lozenges.

### **3. How to use NiQuitin Mint 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 Mint 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 Mint 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 Mint Lozenges for longer than 9 months in total, you should ask a healthcare professional for advice.

## Adults (18 years and over)

NiQuitin 2 mg Mint Lozenges are for smokers who smoke more than 30 minutes after 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 Mint 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 Mint 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 Mint Lozenges than you should

If you use too many NiQuitin Mint 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 Mint 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, swelling of skin or mucous membrane, face, tongue and throat causing breathing difficulties.

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, flatulence.

Common: may affect up to 1 in 10 people  
sore throat, mouth/tongue irritation or ulceration sleep disturbance, headache, anxiety, irritability  
being sick, belching, hiccups, flatulence, diarrhoea, increased appetite, indigestion, heartburn, dry mouth, constipation, pharyngitis (swelling in the back of the throat), coughing, dizziness, dysphagia (difficulty to swallow).

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

Uncommon: may affect up to 1 in 100 people  
abnormal dreams, mood changes, worsening anxiety, feeling angry, wakefulness, abnormal hunger  
worsening asthma or difficulty breathing, difficulty swallowing, chest infections, coughing, nose and throat irritation, nasal congestion  
dry lips, dry throat, jaw or tooth pain, bleeding gums, taste disturbance/distortion, local numbness  
stomach rumbling, worsening indigestion, acid regurgitation, gut irritation, stomach ulcer, hiatus hernia, itching or a rash, localized skin reaction, skin flushes, nosebleed, pain, leg pain or swelling frequent urination at night symptoms of overdose.

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), palpitations (feeling your heart beat), tachycardia (increased heart beat), asthenia (lack of energy), fatigue (tiredness), influenza like illness (flu like symptoms), 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 HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: <http://www.hpra.ie>; e-mail: [medsafety@hpra.ie](mailto:medsafety@hpra.ie).

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

### **5. How to store NiQuitin Mint 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.

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 Mint Lozenges contain**

**The active substance** is nicotine 2 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 spearmint flavour (contains lactose and soya protein).

#### **What NiQuitin Mint Lozenges look like and contents of the pack**

White, round compressed lozenges with convex surfaces.

NiQuitin Mint Lozenges have “NL2S” on one side.

Packs contain 36 or 72 lozenges (blister pack).

*Not all pack sizes may be marketed.*

#### **Marketing Authorisation Holder and Manufacturer**

Authorisation Holder: Chefaro Ireland DAC, The Sharp Building, Hogan Place, Dublin 2, Ireland

Manufacturer: 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 Mint 2 mg

Czech Republic, Slovakia - NiQuitin 2 mg

Hungary - NiQuitin Mentolos 2 mg Szopogató Tabletta

Ireland - NiQuitin 2 mg Mint Lozenge

Italy – NiQuitin 2 mg Pastiglie Gusto Menta

Portugal - NiQuitin 2 mg Comprimidos para chupar

United Kingdom - Nicabate 2 mg Mint Lozenges

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