

## **Package leaflet: Information for the user**

### **NiQuitin Minis 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.
- If you have any further questions, ask a healthcare professional (doctor, nurse, smoking cessation advisor or pharmacist).
- 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 Minis 4 mg Lozenges** are referred to as **NiQuitin Minis**.

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

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

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

**NiQuitin Minis are used to help people stop smoking.** This type of treatment is called **Nicotine Replacement Therapy (NRT)**.

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

- NiQuitin Minis 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 Minis 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.

NiQuitin Minis can be used to help you:

- stop smoking straightaway (a quit attempt).
- cut down on smoking, perhaps before you go on to stop completely (reducing to quit or just reducing).

In addition, NiQuitin Minis can be used when you:

- do not wish to smoke or are unable to smoke, for example in confined spaces (in the car, in the house), where others (such as children) could be harmed by tobacco smoke or in places where smoking is prohibited (temporary abstinence).
- develop cravings once you have stopped smoking.

Reducing the number of cigarettes smoked can increase the chances that you will go on to quit completely.

NiQuitin Minis may be recommended by a healthcare professional during pregnancy and breastfeeding (see Pregnancy and breast-feeding below).

**Your chance of stopping smoking will be improved if you also take part in a support programme.** These ‘Stop Smoking’ programmes are known as behavioural support. For more information, talk to a healthcare professional or:

- call the NHS Free Smoking Helpline on 0800 022 4332, or visit <http://www.smokefree.nhs.uk> [or the Irish National Smokers Quitline on 1850 201 203]
- or visit <http://www.niquitin.co.uk> for information about a free online support plan.

There are no health benefits to smoking. It is always better to give up smoking. Using Nicotine Replacement Therapy (NRT) like NiQuitin Minis 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 Minis**

### **Do not use NiQuitin Minis if:**

- you are allergic to nicotine, or any of the other ingredients of this medicine (listed in Section 6).
- you are a non-smoker.
- you are aged under 12.

### **Warnings and precautions**

Talk to your healthcare professional before using **NiQuitin Minis**:

- 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 have diabetes you should monitor your blood sugar levels more often than usual when you start using NiQuitin Minis. Your insulin or medicine requirements may change.
- If you have 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 serious or moderate liver or kidney problems, because you may be more likely to get side-effects
- If you have 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.
- If you have 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 any concerns about becoming dependent or think you have become dependent on this product.

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.)

### **Children (under 12 years)**

The level of nicotine in NRT is not suitable for children under 12. Nicotine affects children more than adults. It could cause severe poisoning in children which can cause death.

### **Other medicines and NiQuitin Minis**

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.

#### **Pregnancy**

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.

#### **Breast-feeding**

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 Nicotine Minis on the ability to drive or use machines. However, you should be aware that giving up smoking can cause behavioural changes that affect your ability to drive or use machines.

### **Nicotine Minis contain**

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**

Always use NiQuitin lozenges 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 Minis 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.

### **Adults and young people 12 years and over**

Instructions for use of NiQuitin Minis depends on whether you are:

- Stopping smoking straightaway.
- Cutting down on smoking before you stop.
- Cutting down with no immediate plans to stop
- Going without cigarettes for a short time or if you have cravings after you have stopped smoking.

**If you are under 18 years old** and not ready to stop smoking straight away, talk to a healthcare professional for advice.

In all cases:

- NiQuitin Minis 4 mg Lozenges are for smokers who smoke more than 20 cigarettes a day.
- You should put one lozenge in your mouth and periodically move it from one side of your mouth to the other, until it has 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.

**NiQuitin Minis are not suitable for children under 12 years of age or for non-smokers.** They may develop signs of nicotine overdose, including headache, sickness, stomach pain and diarrhoea.

### **Stopping smoking straightaway**

#### **Adults and young people aged 12 years and over:**

- Start by using 8 – 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 – 2 lozenges a day, try to stop using them altogether.

### **Cutting down on smoking before you stop**

#### **Adults aged 18 years and over:**

You may find it easier to quit completely later if you use NiQuitin Minis to help you cut down on smoking first. When you feel a strong urge to smoke, have a lozenge 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 ready to stop smoking completely, follow the instructions above, under 'Stopping smoking straightaway'. If you have not felt able to make a quit attempt within 6 months of starting to use NRT, you may find it helpful to talk to a healthcare professional.

### **Cutting down with no immediate plans to stop**

#### **Adults aged 18 years and over:**

**It is always best to stop smoking completely**, but using NRT to cut down is less harmful than continuing to smoke heavily. Cutting down the number of cigarettes you smoke each day will make it easier to quit completely in the future. When you feel an urge to smoke, have a lozenge 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.

**It is best to stop smoking completely** as soon as you feel able to. Follow the instructions above, under 'Stopping smoking straightaway'.

### **Going without cigarettes for a short time**

#### **Adults aged 18 years and over:**

NiQuitin Minis can help you manage your cravings so that you can resist cigarettes in situations where smoking is inappropriate, for example:

- where your second-hand smoke may damage other people, such as children.
- where smoking is not allowed, such as on a flight or in a hospital.
- when smoking should be avoided, such as before surgery.

When you feel an urge to smoke, have a lozenge instead of a cigarette to help you manage your cravings. Continue to use one lozenge every 1 – 2 hours during the period when you are avoiding smoking.

**It is best to stop smoking completely** as soon as you feel able to. Follow the instructions above, under 'Stopping smoking straightaway'.

### **Once you have stopped smoking...**

After you have stopped smoking, you may still sometimes feel a craving for a cigarette. You can use NiQuitin Minis again to help you relieve these cravings - **using NRT is always better than smoking again.**

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

#### **Adolescents (12-17 years inclusive)**

You should follow the instruction above for stopping smoking straight away, but you should only use the lozenges for 12 weeks in total. If you feel the need to use NiQuitin minis 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.

#### **Children (under 12 years)**

Children under 12 years must not use NiQuitin Minis.

#### **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 Minis than you should**

If you use too many NiQuitin Minis 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 Minis 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 some symptoms such as dizziness, headache, sleep disturbance, cough and cold-like symptoms. 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 grouped 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, sleep disturbance, headache, anxiety, irritability, being sick, belching, flatulence, diarrhoea, increased appetite, indigestion, heartburn, dry mouth, constipation, pharyngitis (swelling in the back of the throat), hiccups, coughing, dizziness.

Uncommon side-effects (may affect *up to* 1 in 100 people)

- an increase in your heart rate or awareness of your heart beat abnormal dreams, mood changes, worsening anxiety, feeling angry, wakefulness, abnormal hunger
- worsening asthma or difficulty breathing, difficulty swallowing, chest infections, 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, redness of the skin, localized skin reaction, increased sweating, 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), 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, nurse or smoking cessation advisor. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects, you can help provide more information on the safety of this medicine.

## 5. How to store NiQuitin Minis

### Keep out of the sight and reach of children.

- Do not use this medicine after the 'EXP' date shown on the container and outer packaging. The expiry date refers to the last day of the month.
- Keep all lozenges in the original container.
- Do not store above 25°C.
- Do not use the container for anything else due to possible fine coating of tablet dust inside.
- Do not throw medicines away 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 contain

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

**The other ingredients** are mannitol, sodium alginate, xanthan gum, potassium bicarbonate, calcium polycarbophil, sodium carbonate anhydrous, acesulfame potassium, mint flavour, sucralose and magnesium stearate. NiQuitin Minis are sugar free.

### What NiQuitin Minis look like and the contents of the pack

White to off-white biconvex oval lozenges. The 4 mg lozenge has "NIC4" on one side.

Each container contains 20 lozenges. Packs may contain one, three or five containers in a blister card or five containers in a carton.

### Marketing Authorisation Holder and Manufacturer

The Marketing Authorisation holder is Omega Pharma Ltd, 32 Vauxhall Bridge Road, London, SW1V 2SA, UK and all enquiries should be sent to this address.

The manufacturer of NiQuitin Minis Mint Lozenges is Wrafton Laboratories Limited, Exeter Road, Wrafton, Braunton EX33 2DL, UK.

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