

NiQuitin Minis[®]

Mint 1.5 mg & 4 mg lozenges

Nicotine

Please read right through this leaflet before you start using this medicine. This medicine is available without prescription, but you still need to use NiQuitin Minis carefully to get the best results from them.

- 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).
- Throughout this leaflet NiQuitin Minis Mint 1.5 mg & 4 mg Lozenges are referred to as NiQuitin Minis.

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1. What NiQuitin Minis do

NiQuitin Minis are used to help people stop smoking. They work by replacing some of the nicotine you get from cigarettes. This type of treatment is called **Nicotine Replacement Therapy (NRT)**.

The nicotine in cigarettes makes them addictive, but other substances in cigarette smoke, such as tar, carbon dioxide and other toxins, are more harmful to your health. **NRT products like NiQuitin Minis do not have the health dangers of tobacco.**

The nicotine from NRT reduces your cravings for cigarettes and helps you resist the urge to smoke. It also relieves some of the unpleasant symptoms (like feeling ill or irritable) that smokers have when they try to give up.

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 can be used during pregnancy and breast-feeding (see *Pregnancy and breast-feeding* below).

Some people worry that, when they have stopped smoking, they may become dependent on NRT instead. This is very rare, and if it were to happen it is still safer than continuing to smoke. It is also an easier habit to break.

It is always better to stop smoking completely. Smoking is harmful and has no health benefits. NRT products like NiQuitin Minis can help you stop. Any risks or possible side-effects of nicotine from NRT are much less than the proven dangers of continuing to smoke.

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:

- 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.

2. Check before you use NiQuitin Minis

Do not use NiQuitin Minis:

- if you have ever had an **allergic reaction** to nicotine, or any of the other ingredients (*listed in Section 6*).
- if you are a **non-smoker**.
- if you are **aged under 12**. The level of nicotine in NRT is not suitable for children under 12. Children are more susceptible to the effects of nicotine, and it could cause severe toxicity, which can be fatal.

Take special care with NiQuitin Minis

Get help and advice from a healthcare professional:

- if you are in **hospital** because you have had a **heart attack**, **severe heart rhythm disturbances** or a **stroke**. Try to stop smoking without NRT unless your doctor has told you to use it. Once you are discharged from hospital, you can use NRT as normal.



- if you have **diabetes**. When you start using NRT, you need to monitor your blood sugar levels more often than usual, because your dose of medication for diabetes may need to be adjusted.
- if you have **serious liver or kidney problems**, because you may be more likely to get side-effects.
- if you have **uncontrolled overactive thyroid gland or an adrenal gland tumour** (phaeochromocytoma), because nicotine may make your symptoms worse.
- if you have **stomach or duodenal ulcers or inflammation of the 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 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.
- before using if you have ever experienced seizures (fits).

If you are taking 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 planning to become pregnant

Smoking when you are pregnant is harmful to the baby. The risks include poor growth before birth, damage to the baby's lungs, premature birth and stillbirth. Stopping smoking is the best way to improve your health and the health of your baby, and the earlier you stop smoking the better.

It is best to give up smoking without using NRT. If that's too difficult, using NRT is safer for you and your baby than continuing to smoke. The nicotine in NRT is less dangerous than the more harmful substances in cigarette smoke, such as tar and other toxins.

If you have tried to stop smoking without using NRT, and haven't been able to, your healthcare advisor may recommend NRT to help you stop. If you do use NRT during pregnancy:

- Start as early in your pregnancy as possible.
- Aim if possible to use NRT for only 2 to 3 months. But remember — the most important thing is not to smoke. It is safer to carry on using NRT than to start smoking again.
- If you can use them, NRT gum or lozenges are better than patches.
That's because you will not be absorbing nicotine into your body all the time. But if you feel sick, you may need to use NRT patches instead.

If you are breast-feeding

Tobacco smoke is harmful to babies and children, causing breathing difficulties and other problems.

If you are breast-feeding, it is best if you stop smoking without using NRT. But if you do need to use NRT, the nicotine that gets into breast milk is less dangerous to your baby than breathing in second-hand smoke.

If you do use NRT while breast-feeding:


- It is better to use NRT gum or lozenges to control your cravings as they happen, rather than patches. With gum or lozenges, you will not be absorbing nicotine into your body all the time.
- Try to breast-feed just before you take the gum or lozenge, when the nicotine levels in your body are at their lowest. That way, your baby gets as little nicotine as possible.

3. How to use NiQuitin Minis

Adults and young people aged 12 years and over

Instructions for use of NiQuitin Minis depend 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 straightaway, talk to a healthcare professional for advice. In all cases:
- **NiQuitin Minis Mint 4 mg Lozenges** are for smokers who smoke *more than* 20 cigarettes a day.
 - **NiQuitin Minis Mint 1.5 mg Lozenges** are for smokers who smoke *fewer 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.

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Stopping smoking straightaway

Adults and young people aged 12 years and over:

It is important to make every effort to stop smoking completely. But if you do sometimes smoke a cigarette while using NRT, don't be discouraged — just keep going with your quit attempt. It may help to talk to a healthcare professional if you are finding your quit attempt difficult.

- 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.

To increase your chances of success follow a stop smoking behavioural support programme – see the end of Section 1 for more details.



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 (maximum 15 a day) 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.

If you are worried that you may start smoking again, talk to a healthcare professional. They can advise you on how to get the best results from further courses of NRT.

If you are finding it difficult to stop using NRT completely, talk to a healthcare professional.



If you use more NiQuitin Minis than you should

If a child has used or eaten any of the lozenges, contact your doctor or hospital emergency department immediately. If possible, show them the NiQuitin Minis packet or this leaflet. Symptoms of nicotine overdose in children include headache, sickness, stomach pain and diarrhoea.

If you take too many lozenges, you may start to feel sick, dizzy and unwell. Stop using the lozenges and contact your doctor or hospital emergency department immediately.

4. Possible side-effects

Like all medicines, the nicotine in NRT products can have side-effects. They are similar to those you might get from the nicotine in cigarettes, and are more likely the more nicotine you take, but not everybody gets them. At the recommended doses NiQuitin Minis have not been found to cause any serious side-effects.

Stopping smoking itself can cause some 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 grouped based on the likelihood with which they can occur.

Very common (affects 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 (affects between 1 in 10 and 1 in 100 people)

- Sore throat
- Being sick
- Stomach discomfort
- Diarrhoea
- Indigestion/heartburn
- Flatulence
- Hiccups

Less common side-effects (affects between 1 in 100 and 1 in 1000 people)

- Nervousness
- Depression
- Palpitations (feeling your heartbeat)
- Increased heartbeat
- Chest pain
- Rash
- Tiredness and generally feeling unwell

Very rare (affects less than 1 in 10,000 people)

- Severe allergic reaction, symptoms of which include sudden wheeziness or tightness of the chest, rash and feeling faint.

If you experience seizures (fits), stop taking this medicine.

If any of the side-effects get serious, or if you notice any side-effects not listed in this leaflet, tell a healthcare professional.

5. How to store NiQuitin Minis

- Keep out of the reach and sight 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 in order to protect from moisture.
- Do not store above 30°C.
- Do not use the container for anything else due to possible fine coating of tablet dust inside.
- 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. Further information

What NiQuitin Minis contain

The active substance is nicotine. Each lozenge contains 1.5 mg or 4 mg (in the form of a resin complex called nicotine resinolate). The other ingredients are mannitol (E 421), sodium alginate (E 401), xanthan gum (E 415), potassium bicarbonate (E 501), calcium polycarbophil, sodium carbonate anhydrous (E 500), acesulfame potassium (E 950), taste masking flavour, peppermint flavour, menthol flavour and magnesium stearate (E 970b).

What NiQuitin Minis look like and the contents of the pack

White to off-white oval lozenges with convex surfaces. The 1.5 mg lozenge has a "L" on one side. The 4 mg lozenge has a "F" on one side.

Each container contains 20 lozenges. Packs may contain one or three containers in a blistercard 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 GlaxoSmithKline Dunganvan Ltd, Knockbrack, Co. Waterford, Ireland.

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