

NiQuitin[®]

2 mg & 4 mg Mint gum
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 Mint Gum carefully to get the best results from it.

- 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).

In this leaflet:

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1. What NiQuitin Mint Gum does

NiQuitin Mint Gum is used to help people stop smoking. It works 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 Mint Gum 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 Mint Gum 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 Mint Gum may 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 Mint Gum 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 Mint Gum 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.

- 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 been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this product. NiQuitin Mint Gum contains sorbitol (E 420).
- 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 are on a low sodium diet. Each piece of gum contains 11.4 mg sodium and the maximum daily dose (15 pieces of gum) contains 171 mg sodium. The maximum daily dose may be harmful if you are on a low sodium diet.



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.



Other things you may need to know:

- NiQuitin Mint Gum contains butylhydroxytoluene (E 321) which may cause irritation to the mouth or the skin around it.
- NiQuitin Mint Gum is sugar-free.
- If you wear dentures (false teeth) that are poorly fitting or not clean you may have difficulty chewing the gum. Another NRT product may be more suitable for you, such as patch or lozenge.



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.

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 Mint Gum



Do not use NiQuitin Mint Gum:

- 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 under **12 years**. 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 Mint Gum

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 quit 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.

- 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 Mint Gum



Adults and young people aged 12 years and over

Instructions for use of NiQuitin Mint Gum 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 4 mg Mint Gum** is for smokers who smoke *within* 30 minutes of waking.
- **NiQuitin 2 mg Mint Gum** is for smokers who smoke *more than* 30 minutes after waking.
- You should put a piece of gum in your mouth and periodically chew it, as described in the instructions below, for about 30 minutes. Dispose of it carefully.
- Do not use more than 15 pieces of gum a day.

NiQuitin Mint Gum is 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:

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.

- Use 8 – 12 pieces of gum a day. Take a piece of gum whenever you have an urge to smoke.
- Use the gum like this for up to 3 months in total, then gradually reduce the number of pieces you use a day.
- Once you are using only 1 – 2 pieces of gum a day, try to stop using it altogether.
- If you started using the 4 mg gum, you can change to the 2 mg gum during the reduction stage.

To increase your chances of success, complete the step down programme in full and 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 Mint Gum to help you cut down on smoking first.

When you feel an urge to smoke, chew a piece of gum instead of having 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.

system through the lining of the mouth. If the nicotine gum is chewed continuously, the nicotine is released too quickly and swallowed. This may irritate your throat, upset your stomach and give you hiccups.

- Chew a piece of gum when you feel the urge to smoke.
- Chew slowly until the taste becomes strong (about 1 minute) then stop and rest the gum against your cheek.
- When the taste fades chew a few times until the taste gets strong then rest the gum again.
- Keep chewing like this for about half an hour.
- When the gum has lost its strong taste you should dispose of it carefully.



If you use more NiQuitin Mint Gum than you should

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

If you take too much gum, you may start to feel sick, dizzy and unwell. Stop using the gum 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 Mint Gum** has not been found to cause any serious side-effects.

Stopping smoking itself can cause some symptoms such as dizziness, headache, sleep disturbance and more mouth ulcers than usual.

Other side-effects may include:

- Troublesome side-effects that do not improve.
- Very rare: Severe allergic reaction symptoms which include sudden wheeziness or tightness of the chest, rash & feeling faint.

Stop taking the gum and tell a healthcare professional if you get these.

- Allergic reactions e.g. swelling, a rapid irregular heartbeat or palpitations (feeling your heart beat).
- Sore/irritated throat, more saliva than usual, hiccups.
- Feeling sick, stomach pains, jaw ache.
- Red or itchy skin.

Tell a healthcare professional if you get any of these.

If you wear dentures it is possible that the gum may stick to them or, in rare cases, damage them.

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 future.

When you feel an urge to smoke, chew a piece of gum instead of having 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 Mint Gum 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, chew a piece of gum instead of having a cigarette to help you manage your cravings. Continue to use one piece of gum 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 Mint Gum 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.

How to use the gum

The method of chewing nicotine gum is not the same as for ordinary chewing gum. The gum is chewed to release nicotine then rested, so that nicotine can be taken into your

blood. If you do get any side-effects, even those not mentioned in this leaflet, tell a healthcare professional.

5. How to store NiQuitin Mint Gum

- Keep out of the reach and sight of children.
- Do not use this medicine after the 'EXP' date shown on the blister pack and outer packaging. The expiry date refers to the last day of the month.
- Keep all pieces of gum in the carton, in their blister pack, until you are ready to use one.
- Do not store above 25°C.
- 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 Mint Gum contains

The active substance is nicotine. Each piece of gum contains 2 mg or 4 mg (in the form of a resin complex called nicotine resinates). The other ingredients are chewing gum base, calcium carbonate, butylhydroxytoluene (E 321) as an antioxidant, sorbitol (E 420), maltitol liquid, glycerol, acesulfame potassium, flavour, mannitol (E 421), sodium carbonate anhydrous, sodium hydrogen carbonate and carnauba wax. NiQuitin 4 mg Mint Gum also contains colour quinoline yellow (E 104).

What NiQuitin Mint Gum looks like and the contents of the pack

Rectangular, pillow-shaped gum. The 2 mg gum is off-white and the 4 mg gum is yellow. Packs contain 12, 24 or 96 pieces.

Marketing Authorisation Holder and Manufacturer

The Marketing Authorisation holder is GlaxoSmithKline Consumer Healthcare, Brentford, TW8 9GS, U.K. and all enquiries should be sent to this address.

The manufacturer of NiQuitin Mint Gum is Fertin Pharma A/S, 7100 Vejle, Denmark.

If you have any questions or comments about NiQuitin Mint Gum, please FREEPHONE our Information Line on 0500 100 222 or e-mail customer.relations@gsk.com.

NiQuitin is a registered trade mark of the GlaxoSmithKline group of companies.



This leaflet was last revised in February 2011.