

Package leaflet: Information for the user

NiQuitin Fresh Mint 2 mg or 4mg medicated chewing gum

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 advisor 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.
- You must talk to a doctor if you have not been able to stop smoking after 9 months of treatment with NiQuitin Fresh Mint 2 mg or 4mg Medicated Chewing Gums.
- Throughout this leaflet NiQuitin Fresh Mint 2 mg and 4 mg Medicated Chewing Gums are referred to as NiQuitin Fresh Mint Gums.

What is in this leaflet

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1. What NiQuitin Fresh Mint Gums are and what they are used for

NiQuitin Fresh Mint Gums 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 Fresh Mint Gums 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 Fresh Mint Gums 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 gums 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 or a pharmacist.

There are no health benefits to smoking. It is always better to give up smoking. Using Nicotine Replacement Therapy (NRT), like NiQuitin Fresh Mint Gums, 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 Fresh Mint Gums

Do not use NiQuitin Fresh Mint Gums:

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

Warnings and precautions

Talk to your healthcare professional before using NiQuitin Fresh Mint Gums:

- If you have had a recent heart attack or stroke, or you suffer from severe heart rhythm problems, unstable or worsening angina (chest pain) high blood pressure which is not controlled by medication 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 Fresh Mint Gums. 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 wear dentures as you may experience difficulties in chewing.
- Chewing Nicotine gum may loosen fillings or dental implants.
- Nicotine replacement Therapy (NRT) is not suitable for children under 12. The effects of nicotine affect children more than adults. It could cause a severe poisoning in children which can cause death.

Do not interchange between NiQuitin Fresh Mint Gums and nicotine lozenges during any attempt to quit smoking.

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

- Severe or moderate liver or severe or moderate 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.
- Stomach or duodenal ulcer or an inflamed oesophagus or gullet (the passage between the mouth and the 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.

Children (under 12 years)

The correct dose for adults could seriously poison or be fatal to small children. It is therefore essential that you keep NiQuitin Fresh Mint Gums out of sight and reach of children at all times.

Other medicines and NiQuitin Fresh Mint Gums

Tell your healthcare professional if you are using, have recently used or might use any other medicines.

Stopping smoking may alter the effects of other medicines you may be taking. If you have any questions or concerns about this talk to a healthcare professional.

This is especially important if you use other medicines which contain:

- theophylline (to treat asthma)
- tacrine (for Alzheimer's disease)
- clozapine (for schizophrenia)
- ropinirole (to treat Parkinson's disease)

NiQuitin Fresh Mint Gums with food and drink

You should not eat or drink while NiQuitin Fresh Mint Gums are in your mouth.

Acidic drinks (e.g. fruit juice, coffee or soda) influence the uptake of nicotine in the mouth cavity. To make sure that the best effect is achieved, you should avoid such drinks approximately 15 minutes prior to using NiQuitin Fresh Mint Gums.

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your healthcare professional for advice before using 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 gums may be preferable to nicotine patches. This is because with gums, you do not get the nicotine all the time. However, patches may be preferred if you have nausea or sickness.

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 best to use NRT products that are taken at certain times of the day (such as gums or lozenges, 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 Fresh Mint Gums 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 Fresh Mint Gums contain

- Sodium – This medicinal product contains less than 1mmol sodium (23 mg) per piece of gum, that is to say essentially ‘sodium free’.
- Sorbitol (E420) - Each 2 mg gum contains 148.65 mg of sorbitol. Each 4mg gum contains 137.55 mg of sorbitol. Sorbitol is a source of fructose. If your doctor has told you that you have an intolerance to some sugars or if you have been diagnosed with hereditary fructose intolerance (HFI), a rare genetic disorder in which a person cannot break down fructose, talk to your doctor before you take or receive this medicine.
- Butylated hydroxytoluene (E321) – May cause local skin reactions (e.g. contact dermatitis), or irritation to the eyes and mucous membranes.

3. How to use NiQuitin Fresh Mint Gums

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 Fresh Mint Gums 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.

NiQuitin Fresh Mint Gums 2mg are for smokers who smoke less than 20 cigarettes a day.
NiQuitin Fresh Mint Gums 4mg are for smokers who smoke 20 or more cigarettes a day.

Do not chew NiQuitin Fresh Mint Gum as ordinary chewing-gum. If NiQuitin Fresh Mint Gum is chewed too quickly and without breaks, nicotine is released too quickly. This may cause discomfort (e.g. heartburn and hiccups).

You should use NiQuitin Fresh Mint Gums by peeling the paper off and pushing a piece of gum out. Then put one gum in your mouth and 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. After about 30 minutes of such use, the gum will be exhausted. You should not eat or drink while a gum is in your mouth as this may reduce the uptake of the nicotine. Do not use more than 15 gums a day. If you feel the need to use NiQuitin Fresh Mint Gums for longer than 9 months in total, you should ask a healthcare professional for advice.

NiQuitin Fresh Mint Gums can be used according to the following timetable which is designed to gradually reduce the number of pieces of gum you use.

Adults (18 years and over)

- Start by using 8 to 12 gums a day. Chew gum whenever you have an urge to smoke.
- Use the gums like this for up to 3 months, then gradually cut down the number of gums you use a day (see table below).
- Once you are using only 1 or 2 gums 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 gum again if it happens.

STEP 1	STEP 2	STEP 3
Initial treatment period Chew 1 piece of gum whenever	Step down treatment period Gradually reduce gum use to 1-2	Support treatment Chew a piece of gum if sudden
there is an urge to smoke. Use 8-12 pieces/day for up to 3 months.	pieces/day. Then stop treatment.	cravings tempt you to smoke.

Use in children and adolescents

Adolescents (12-17 years inclusive)

Adolescents should not use Nicabate Extra Fresh Gums without recommendation from a doctor.

Do not exceed the stated dose. Do not smoke or use any other nicotine containing product at the same time. Follow the instruction carefully and do not use more than 15 gum pieces in one day (24 hours).

Children under 12 years

Children under 12 years of age must not use NiQuitin Fresh Mint Gums.

If you are tempted to start smoking again

If you are worried that you may start smoking again or finding it difficult to stop using the gums 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 NRT.

If you use more NiQuitin Fresh Mint Gums than you should

If you use too many NiQuitin Fresh Mint Gums you may start to feel sick, dizzy and unwell. Stop using the gums and get advice straightaway from a doctor or hospital casualty department. If possible, show them the packet or this leaflet.

The gums are not suitable for children under 12. If the gums are used by children 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 gums, contact your doctor or nearest hospital casualty department straightaway as this may be very dangerous and even fatal. 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 Fresh Mint Gums have not been found to cause any serious side effects.

Stopping smoking itself can cause symptoms such as dizziness, headache, sleep disturbances, cough, cold-like symptoms. Symptoms such as depression, irritability, anxiety, increased appetite and insomnia may also be related to withdrawal symptoms associated with giving up smoking.

Stop taking NiQuitin Fresh Mint Gums and see a doctor immediately if you experience any of the following symptoms of allergic reactions, which can be serious:

Very rare side effects (may affect up to 1 in 10,000 people)

- swollen face, tongue or throat
- difficulty to swallow
- hives and difficulties with breathing
- irregular heartbeat
- severe allergic reaction symptoms of which include sudden wheeziness or tightness of chest, rash and feeling faint

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

- feeling sick

Common (may affect up to 1 in 10 people)

- gastro-intestinal discomfort
- sore throat, sore/dry mouth, mouth irritation or ulceration, pharyngitis, cough
- sleep disturbance, headache, irritability, dizziness
- being sick, hiccups, indigestion, flatulence, diarrhoea, constipation
- jaw pain

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

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

- an increase in your heart rate or awareness of your heart beat
- difficulty breathing, chest pain
- taste disturbance/distortion
- redness of the skin, hives, increased sweating
- pain in muscles/joint or swelling
- inflammation of the mucous lining of the mouth
- tremor
- feeling unwell

Not known (frequency cannot be estimated from the available data)

- seizures (fits), difficulty to swallow, burping, increased salivation, asthenia (lack of energy), fatigue (tiredness), influenza type illness (flu like symptoms), hypersensitivity, abnormal dreams, itching or a rash, numbness or tingling in the mouth.

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, Website: www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store NiQuitin Fresh Mint Gums

- **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 after EXP. The expiry date refers to the last day of that month.
- Do not store above 25°C.
- Store in the original container.
- Do not throw any medicine 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 Fresh Mint Gums contain:

- The active substance is nicotine. Each gum piece contains 2 mg or 4 mg (in the form of a resin complex called nicotine resinate).
- The other ingredients are:
Gum contains Butylated hydroxytoluene (E321), Sorbitol (E420), Xylitol (E967), Calcium Carbonate (E170), Sodium Carbonate Anhydrous (E500), Glycerol (E422), Acesulfame Potassium (E950), Mannitol (E421), Acacia (E414), Sucralose (E955), Titanium Dioxide (E171), and Flavours: Optacool, Eucamenthol and Levomenthol

What NiQuitin Fresh Mint Gums look like and contents of the pack

White to off-white rectangular shaped chewing gum Each blister contains 4 or 10 gum pieces. Pack contains 4, 10, 30, 100 or 200 gum pieces. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Chefaro Ireland DAC
The Sharp Building Hogan Place
Dublin 2
Ireland.
All enquiries should be sent to this address.

Manufacturer

Fertin Pharma AS
Dandyvej 19
Vejle, DK-7100
Denmark.

Logiters, Logistica Portugal, S.A.
Estrada dos Arneiros, 4,
Azambuja, 2050 – 544

Portugal

This medicine is authorised in the Member States of the European Economic Area and in the United Kingdom (Northern Ireland) under the following names:

Belgium	NiQuitin freshmint 2 mg & 4mg Gomme à mâcher médicamenteuse
Croatia	NiQuitin GUM Icy Fresh Mint 2 mg & 4mg ljekovita guma za žvakanje
Czech Republic	NiQuitin Freshmint
Estonia	NiQuitin Mint 2 mg & 4 mg ravimnäriskumm
Hungary	NiQuitin Menthol Fresh 2 mg & 4mg gyógyszeres rágógi
Ireland	NiQuitin Fresh Mint 2mg & 4mg Medicated Chewing Gum
Latvia	NiQuitin Mint 2 mg & 4mg ārstnieciskā košļājamā gumiņa
Lithuania	NiQuitin Mint 2 mg & 4mg vaistinė kramtomoji guma
Luxembourg	NiQuitin freshmint 2 mg & 4mg Gomme à mâcher médicamenteuse
Netherlands	NiQuitin Mint 2 mg & 4 mg Kauwgom
Poland	NiQuitin Extra Fresh 2mg & 4 mg guma do żucia, lecznicza
Portugal	NiQuitin Mint 2mg & 4 mg gomas para mascar medicamentosas
Slovakia	NiQuitin Freshmint 2 mg & 4 mg mg liečivé žuvačky
Spain	NiQuitin Mint 2 mg & 4 mg chicles medicamentosos
Sweden	NiQuitin Mint 2 mg & 4 mg medicinskt tuggummi
United Kingdom (Northern Ireland)	Nicabate Extra Fresh Mint 2 mg or 4mg Medicated Chewing Gum

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