File title:	**11446_LF21665D_CR07561_NiQuitin Lozenge Mint 2mg 72s_Leaflet_UK_v3**
Item No.:	H9V00SXJ6 - Leaflet [Generic]
OPI No.:	LF21665D
Replacement No.:	H9V00SXJ4 - Leaflet [Generic]
Last edit:	26th January 2023
Brand:	NiQuitin
Variant:	Lozenge Mint 2mg 132s
Component:	Leaflet (shared with 4mg and all pack sizes)
Market/s:	United Kingdom
Dimensions:	140x420mm
Reel Unwind:	...
Spec. Ref.:	L629D003/05
Substrate:	Paper
PharmaCode:	1661
EAN Code:	...
Other Code/Spec.:	...
Manufacturing Site:	Wrafton Laboratories LTD
Printer:	Essentra - Newmarket
Print process:	Litho
No. of Colours:	1

Black Cutter

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512 Metal Box Factory,
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PACKAGE LEAFLET: INFORMATION FOR THE USER

NiQuitin Mint 2 mg and 4mg 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 doctor, pharmacist or nurse has told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- You must talk to a doctor if you do not feel better or if you feel worse after 6 months
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

IN THIS LEAFLET:

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

1. What NiQuitin Mint 2mg and 4mg Lozenges are and what they are used for

NiQuitin Mint 2mg and 4mg Lozenges are used to help people stop smoking. This type of treatment is called Nicotine Replacement Therapy (NRT).

NiQuitin Mint 2mg and 4mg Lozenges can reduce your urge to smoke by providing some of the nicotine previously inhaled from cigarettes and helps you resist cigarettes.

NiQuitin Mint 2mg and 4mg Lozenges do not have the health dangers of tobacco because they do not contain the tar or carbon monoxide of cigarette smoke.

This medicine contains:

- **nicotine resin** which when sucked, nicotine is released slowly from the resin and absorbed through the lining of the mouth. This nicotine relieves some of the cravings and unpleasant withdrawal symptoms, such as feeling ill or irritable, that smokers frequently feel when they try to give up.

If possible, when giving up smoking these lozenges should be used with a stop smoking behavioural support programme. For further information talk to your healthcare professional.

2. What you need to know before you take NiQuitin Mint 2mg and 4mg Lozenges

Do not take this medicine if you:

- are **allergic** to nicotine or any of the other ingredients (listed in section 6)
- are a non-smoker
- are under 12 years of age.
- suffer from phenylketonuria, a rare inherited metabolic disorder
- are allergic to soya or peanut, because this product contains soya oil

Warnings and precautions

Talk to your doctor, pharmacist or nurse before using NiQuitin Mint 2mg and 4mg Lozenges if you:

- have **heart or circulation** problems including **heart failure or stable angina** (episodes of chest discomfort that are usually predictable)
- have a recent **myocardial infarction**, **unstable** or **worsening angina pectoris** including Prinzmetal angina or a recent cardiovascular accident. You are encouraged to stop smoking without any nicotine replacement therapy (NRT) unless your doctor tells you to use them.
- have **high blood pressure**
- have occlusive **peripheral artery disease** - which is a narrowing of the blood vessels outside of your heart
- have moderate to **serious liver** or **kidney** problems because you may be more likely to get side effects

stomach), dry lips, dry throat, tongue disorder, tooth ache
- parageusia (bad taste in the mouth), metallic taste, taste perversion
- erythema (skin redness), itching, rash, localised skin reaction, increased sweating, urticaria (hives)
- jaw pain
- nocturia (needing to urinate during the night)
- overdose effect, pain, leg pain, build-up of fluid in the legs

Rare may affect up to 1 in 1,000 people:
- Hypersensitivity

Not known frequency cannot be estimated from the available data:
- fits
- swelling of skin or mucous membrane, face, tongue and throat causing breathing difficulties
- taste disturbance/distortion
- tingling mouth
- increased salivation

If you get any side effects, talk to your doctor or pharmacist. This includes any side effects not listed in this leaflet.

Reporting of suspected adverse reactions

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 the Yellow Card Scheme at: 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 Mint 2mg and 4mg Lozenges

Keep all medicines out of the sight and reach of children.

Do not use this medicine after the expiry date printed on the pack. Do not store above 25°C and keep in the original carton.

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. Contents of the pack and other information

What this medicine contains

The active ingredient is nicotine. Each lozenge contains 2 mg or 4 mg (in the form of a resin complex called nicotine resinate).

The other ingredients are: mannitol (E421), magnesium stearate, sodium alginate, xanthan gum, potassium bicarbonate, sodium carbonate anhydrous, aspartame (E951) and peppermint flavour.

What your medicine looks like and contents of the pack:

Cream / white circular compressed lozenge with an odour of peppermint.

The 2 mg lozenge is embossed with L344,on one side. The 4 mg lozenge is embossed with L873 on one side.

Your lozenges are available in pack sizes of 12, 36, 72, 132, 144 and 204's. Not all pack sizes may be marketed.

Marketing Authorisation Holder

Omega Pharma Limited,
Wrafton, Braunton, Devon, EX33 2DL, UK.

Manufacturer(s)

Wrafton Laboratories Limited, Wrafton,
Braunton, Devon, EX33 2DL, United Kingdom

Omega Pharma International NV, Venecoweg 26, Nazareth, 9810, Belgium

The leaflet was revised in: July 2022

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Do not chew the lozenge or swallow it whole. **If you feel the need to use *NiQuitin Mint 2mg and 4mg Lozenges* for longer than 6 months in total, you should ask 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).

Adults (aged 18 years and over):

The recommended treatment schedule is:

STEP 1		STEP 2		STEP 3	
Weeks 1 to 6		Weeks 7 to 9		Weeks 10 to 12	
Initial treatment period		Step down treatment period		Step down treatment period	
1 lozenge every 1 to 2 hours		1 lozenge every 2 to 4 hours		1 lozenge every 4 to 8 hours	

During weeks 1-6 it is recommended that you take at least 9 lozenges per day.

After you have given up you may sometimes feel a sudden craving for a cigarette. You can use a lozenge again if this happens.

Adolescents (aged 12-17 years inclusive):

You should only use *NiQuitin Mint Lozenges* following advice from a healthcare professional

Children under 12 years of age should not use NiQuitin Mint Lozenges.

Information: You are more likely to quit smoking when using this product with help from your pharmacist, doctor, a trained counsellor, or a support programme.

If you use more NiQuitin Mint 2mg and 4mg Lozenges than you should

If you take more than the recommended number of lozenges per day, you may suffer a nicotine overdose and need to get advice from your doctor. Signs of overdose include headache, sickness, stomach pains and diarrhoea.

In the event that a child has taken any lozenges or if an accidental overdose occurs, contact your doctor or nearest hospital casualty department immediately as this could be fatal. If possible show them the pack or this leaflet.

If you forget to take NiQuitin Mint 2mg and 4mg Lozenges

Do not take a double dose to make up for a forgotten dose.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects although not everybody gets them. They are similar to those you might get from the nicotine you take.

Stopping smoking itself can cause symptoms such as dizziness, headache, sleep disturbance, cough and cold-like symptoms, depression, irritability, anxiety and night-time awakening.

Stop taking the lozenges immediately and tell a healthcare professional if you get these symptoms:

Uncommon may affect of 1 in 100 people:
- tachycardia (heart beating too fast)
- peptic (stomach) ulcer, belching, abdominal pain, vomiting, loss of appetite,
- dysphagia (difficulty swallowing)

Very rare may affect up to 1 in 10,000 people:
- anaphylactic reactions (severe allergic reaction symptoms which include sudden wheezines or tightness of the 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 people:
- headache, dizziness
- nausea

Common may affect up to 1 in 10 people:
- insomnia (difficulty sleeping), anxiety, irritability, increased appetite
- tremor, pharyngitis (sore throat)
- cough, hiccups, dyspnoea (shortness of breath)
- vomiting, heartburn, indigestion, hiccup, mouth irritation, mouth ulceration, tongue ulceration, diarrhoea, belching, flatulence (wind), abdominal pain upper, dry mouth, constipation, oral discomfort
- asthenia, fatigue, malaise, influenza like illness

Uncommon may affect up to 1 in 100 people
- gingival bleeding (bleeding gums), nosebleed, abnormal hunger, mood swings, wakefulness
- anger, aggravated anxiety, abnormal dreaming,
- localised numbness
- palpitations (feeling your heartbeat)
- laryngismus (throat spasms), aggravated asthma, lower respiratory tract infection, coughing, nasal irritation, throat irritation, nasal congestion
- peptic ulcer, gastroesophageal reflux, hiatus hernia, oesophagitis (inflammation of the oesophagus), borborygmus (rumbling stomach) ulcer or **inflammation of the oesophagus** (oesophagitis), which is the tube leading from the mouth to the stomach, NRT can make symptoms worse
- have an uncontrolled, **over active thyroid** gland or phaeochromocytoma (a tumour of the adrenal gland that can affect blood pressure). Nicotine may make symptoms worse
- are **diabetic**, as diabetic patients need to monitor blood sugar levels more closely as nicotine from smoking or from taking these lozenges may vary them more than usual
- have had **allergic reactions** (see also section 4 "Possible side effects").
- are taking anti-epileptic drugs or have a history of epilepsy (fits) as cases of convulsions have been reported in association with nicotine
- have any concerns about becoming dependent or think you have become dependent on this product

Other important information:

When you stop smoking your metabolism slows down and this may alter the way your body responds to certain medicines.

Children and adolescents

NiQuitin Mint 2mg and 4mg Lozenges are NOT for use in children and adolescents under 12 years of age.

Other medicines and *NiQuitin Mint 2mg and 4mg Lozenges*

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

***NiQuitin Mint 2mg and 4mg Lozenges* with food and drink**

Do not eat or drink while a lozenge is in the mouth. Avoid liquids which lower the pH in the mouth such as coffee, juices and soft drinks, for up to 15 minutes before the lozenge is used.

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 doctor or pharmacist for advice before taking this medicine.

If you are pregnant or breast-feeding it is best if you can give up smoking without the use of NRT. However, if you have tried and this has not worked, NRT may be recommended by a healthcare professional to help you stop smoking.

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.

The decision to use NRT should be made as early on in your pregnancy as possible. Aim to use NRT for only 2 to 3 months.

If you are breast-feeding tobacco smoke causes breathing difficulties and other problems in babies and children. If you need to use NRT, the amount of nicotine your baby may get is smaller and less harmful than breathing in second-hand smoke. It is better to breastfeed just before you take the product - this helps your baby to get the smallest amount of nicotine possible.

Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines

There are no known effects of these 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 you in this way.

NiQuitin Mint 2mg and 4mg Lozenges contain aspartame, mannitol and sodium.

Sodium: This medicinal product contains less than 1 mmol sodium (23mg) per lozenge, that is to say essentially sodium free.

Aspartame (E951): This medicine contains 6.1mg aspartame in each lozenge. Aspartame is a source of phenylalanine. It may be harmful if you have phenylketonuria (PKU), a rare genetic disorder in which phenylalanine builds up because the body cannot remove it properly.

Mannitol (E421): May have a mild laxative effect. Your lozenges are **sugar free**.

3. How to take NiQuitin Mint 2mg and 4mg Lozenges

Important: *NiQuitin Mint 4mg Lozenges* are suitable for smokers who smoke within 30 minutes of waking. *NiQuitin Mint 2mg Lozenges* are suitable for smokers who have their first cigarette of the day more than 30 minutes after waking up.

Always use Nicotine Lozenges exactly as described in this leaflet. Check with your pharmacist if you are not sure.

The product is for oromucosal use. That means that the nicotine in the lozenge is released slowly into the mouth from where it is absorbed into the body.

In all cases you should use NiQuitin Mint Lozenges by putting one lozenge in your mouth and from time to time move it from one side of your mouth to the other, until it is completely dissolved. This should take around 20-30 minutes.

In most cases the nicotine in the lozenge is released slowly into the mouth from where it is absorbed into the body.

Do not take this medicine if you:

- are **allergic** to nicotine or any of the other ingredients (listed in section 6)
- are a non-smoker
- are under 12 years of age.
- suffer from phenylketonuria, a rare inherited metabolic disorder
- are allergic to soya or peanut, because this product contains soya oil

Warnings and precautions

Talk to your doctor, pharmacist or nurse before using NiQuitin Mint 2mg and 4mg Lozenges if you:

- have **heart or circulation** problems including **heart failure or stable angina** (episodes of chest discomfort that are usually predictable)
- have a recent **myocardial infarction**, **unstable** or **worsening angina pectoris** including Prinzmetal angina or a recent cardiovascular accident. You are encouraged to stop smoking without any nicotine replacement therapy (NRT) unless your doctor tells you to use them.
- have **high blood pressure**
- have occlusive **peripheral artery disease** - which is a narrowing of the blood vessels outside of your heart
- have moderate to **serious liver** or **kidney** problems because you may be more likely to get side effects

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116mm | 12mm | 12mm | 140mm | 190mm | 210mm | 420mm | 10mm

124mm | 8mm | 8mm | 140mm | 190mm | 210mm | 420mm | 10mm