protect the environment. longer required. These measures will help to pharmacist how to dispose of medicines no wastewater or household waste. Ask your Medicines should not be disposed of via and keep in the original carton. Printed on the pack. Do not store above 25°C Do not use this medicine after the expiry date reach of children. Keep all medicines out of the sight and Smg and 4mg Lozenges 5. How to store MiQuitin Mint more information on the safety of this By reporting side effects you can help provide Apple App Store. The leaflet was revised in: January 2022 AHMA Yellow Card in the Google Play or www.mhra.gov.uk/yellowcard or search for 26, Nazareth, 9810, Belgium Yellow Card Scheme at: Omega Pharma International NV, Venecoweg You can also report side effects directly via the Braunton, Devon, EX33 2DL, United Kingdom possible side effects not listed in this leaflet. Wrafton Laboratories Limited, Wrafton, pharmacist or nurse. This includes any Manufacturer(s) If you get any side effects, talk to your doctor, Reporting of suspected adverse reactions Road, London, SW1V 2SA, UK. Omega Pharma Limited, 32 Vauxhall Bridge not listed in this leatlet. or pharmacist. This includes any side effects Marketing Authorisation Holder If you get any side effects, talk to your doctor шау ве тагкетеа. IUCLGSSGG SSIIVSTION 36, 72, 132, 144 and 204's. Not all pack sizes ujnom gailgail • Your lozenges are available in pack sizes of 12,1 • taste disturbance/distortion .9bis and no 818. difficulties one side. The 4 mg lozenge is embossed with Tongue and throat causing breathing The 2 mg lozenge is embossed with L344 an swelling of skin or mucous membrane, face, with an odour of peppermint. Cream / white circular compressed lozenge from the available data: Mot known frequency cannot be estimated coureurs of the pack: What your medicine looks like and hypersensitivity Rare may affect up to 1 in 1,000 people: peppermint flavour. carbonate anhydrous, aspartame (E951) and s6əj əyj ui pinji dnm, potassium bicarbonate, sodium overdose effect, pain, leg pain, build-up of magnesium stearate, sodium aiginate, xantnar • uocınus (ueeqiud 10 nuusie anuud 10e uidur) The other ingredients are: mannitol (E421), e law pain complex called nicoune resinate). nuicana (hives) contains 2 mg or 4 mg (in the form of a resin localised skin reaction, increased sweating, The active ingredient is nicotine. Each lozenge erythema (skin redness), itching, rash, taste, taste perversion What this medicine contains barageusia (bad taste in the mouth), metallic other information disorder, tooth ache 6. Contents of the pack and stomach), dry lips, dry throat, tongue

PACKAGE LEAFLET: INFORMATION FOR THE USER

## NiQuitin Mint 2 mg and 4mg Lozenges

Read all of this leaflet carefully before you This medicine contains: 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

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

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

I. 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.

 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

 have heart or circulation problems including heart failure or stable angina (episodes of chest discomfort that are usually predictable) have a recent mvocardial 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

oesobysaus), borboryamus (rumbling hernia, oesophagitis (inflammation of the • peptic ulcer, gastroesophageal reflux, hiatus nasal congestion

coughing, nasal irritation, throat irritation, asthma, lower respiratory tract infection, • laryngismus (throat spasms), aggravated vascular disorder, flushing palpitations (feeling your heartbeat) localised numbhess

abnormal hunger, mood swings, wakefulness • anger, aggravated anxiety, abnormal dreaming, • gingival bleeding (bleeding gums), nosebleed Uncommon may affect up to 1 in 100 people • asthenia, tatigue, malaise, influenza like illness

discomfort pain upper, dry mouth, constipation, oral

alarmoea, berching, fiatulence (wind), abdominal irritation, mouth ulceration, tongue ulceration, • vomiting, heartburn, indigestion, hiccup, mouth conâp' piccuba, dyspnoea (shortness of breath) tremor, pharyngitis (sore throat)

iuckeased appetite insomnia (difficulty sleeping), anxiety, irritability, Common may affect up to 1 in 10 people:

> • peadache, dizziness • ususea :ejdoed

Very common may affect more than 1 in 10 on the likelihood with which they can occur: Other side effects are listed below- they are based! tightness of the chest, rash and feeling faint). symptoms which include sudden wheeziness or

• anaphylactic reactions (severe allergic reaction Very rare may affect up to 1 in 10,000 people: dysphagia (difficulty swallowing) pain, vomiting, loss of appetite,

• peptic (stomach) ulcer, belching, abdominal tachycardia (heart beating too fast) Uncommon may affect up to 1 in 100 people:

tell a healthcare professional if you get these Stop taking the lozenges immediately and irritability, anxiety and night-time awakening. condh and cold-like symptoms, depression,

such as dizziness, headache, sleep disturbance, Stopping smoking itself can cause symptoms nicotine in cigarettes, and are more likely the more are similar to those you might get from the effects although not everybody gets them. They

4. POSSIBLE SIDE EFFECTS

dissolved. This should take around 20-30

In all cases you should use NiQuitin Mint

described in this leaflet. Check with your

Always use Micotine Lozenges exactly as

cigarette of the day more than 30 minutes after

minutes of waking. NiQuitin Mint 2mg Lozenges

are suitable for smokers who have their first

suitable for smokers who smoke within 30

Important: NiQuitin Mint 4mg Lozenges are

Zmg and 4mg Lozenges

3. How to take MiQuitin Mint

have phenylketonuria (PKU), a rare genetic

aspartame in each lozenge. Aspartame is a

Mannitol (E421): May have a mild laxative effect.

source of phenylalanine. It may be harmful if you

Aspartame (E591): This medicine contains 6.1mg

1 mmol sodium (23mg) per lozenge, that is to say

NiQuitin Mint 2mg and 4mg Lozenges contain

cause behavioural changes that could affect you

you should be aware that giving up smoking can

There are no known effects of these lozenges on

Ask your doctor or pharmacist for advice before

product - this helps your baby to get the smallest

harmful than breathing in second-hand smoke. It

and children. If you need to use NRT, the amount

breathing difficulties and other problems in babies

If you are breast-feeding tobacco smoke causes

on in your pregnancy as possible. Aim to use NRT

The decision to use NRT should be made as early

of nicotine your baby may get is smaller and less

is better to breastfeed just before you take the

your ability to drive or use machines. However,

Sodium: This medicinal product contains less than!

disorder in which phenylalanine builds up because

pharmacist if you are not sure.

Your lozenges are sugar free.

essentially sodium free.

in this way.

aspartame, mannitol and sodium.

Driving and using machines

amount of nicotine possible.

taking any medicine.

for only 2 to 3 months.

your mouth to the other, until it is completely

and from time to time move it from one side of

Lozenges by putting one lozenge in your mouth

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

The product is for oromucosal use. That means that

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

Like all medicines, this medicine can cause side

torgotten dose.

səbuəzon bwb

If you forget to take NiQuitin Mint 2mg and

Do not take a double dose to make up for a

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

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

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

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

use MiQuitin Mint Lozenges.

Children under 12 years of age should not following advice from a healthcare professional segnezod friiM nifiwDiIM ezu ylno bluodz uoY Adolescents (aged 12-17 years inclusive): ozenge again if this happens.

sudden craving for a cigarette. You can use a After you have given up you may sometimes feel a take at least 9 lozenges per day. During weeks 1-6 it is recommended that you

1 to 2 hours | 2 to 4 hours | 4 to 8 hours | **|ozeuđe** ekelk | **| |ozeuđe** ekelk | **| | |ozeuđe** ekelk treatment period treatment period treatment period Step down arep down nitia Weeks 7 to 9 | Weeks 10 to 12 Weeks 1 to 6

STEP 2

STEP 3

he recommended treatment schedule is:

STEP 1

Adults (aged 18 years and over): than 15 lozenges in one day (24 hours). instructions carefully and do not use more Do not exceed the stated dose. Follow the

professional for advice. in total, you should ask a healthcare and 4mg Lozenges for longer than 6 months you teel the need to use MiQuitin Mint 2mg Do not chew the lozenge or swallow it whole. If

The earlier you stop smoking the better. to improve both your nealth and that of your paby. pirtn or stillbirtn. Stopping smoking is the best way I hese include poor growth before birth, premature Smoking during pregnancy has risks for the baby.

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

raking rnis medicine. sek your doctor or pharmacist for advice belore way be pregnant or are pianning to nave a baby, It you are pregnant or breast-reeding, think you Pregnancy, preast-reeding and rertility

The to 15 minutes before the lozenge is used. mouth such as coffee, juices and soft drinks, for mouth. Avoid liquids which lower the pH in the

Do not eat or drink while a lozenge is in the food and drink iw səgnəzod gm4 bns gm2 tniM ni

brescription. /including medicines obtained without a taking or have recently taken any other medicines, the body cannot remove it properly. Please tell your doctor or pharmacist if you are səɓuəzoŋ ɓwt

Other medicines and NiQuitin Mint 2mg and

nee in children and adolescents under 12 years of NiQuitin Mint 2mg and 4mg Lozenges are NOT for Children and adolescents responds to certain medicines.

down and this may after the way your body When you stop smoking your metabolism slows Ofher important information:

broduct

or think you have become dependent on this • have any concerns about becoming dependent been reported in association with nicotine of epilepsy (fits) as cases of convulsions have are taking anti-epileptic drugs or have a history

4 "Possible side effects"). • have had allergic reactions (see also section lozenges may vary them more than usual nicotine from smoking or from taking these

monitor blood sugar levels more closely as • are diabetic, as diabetic patients need to pressure). Nicotine may make symptoms worse of the adrenal gland that can affect blood gland or phaeochromocytoma (a tumour

• have an uncontrolled, over active thyroid NRT can make symptoms worse tube leading from the mouth to the stomach, the oesophagus (oesophagitis), which is the

have a stomach ulcer or inflammation of