Galpharm Nicotine Replace 2mg Lozenges

Nicotine

PATIENT INFORMATION LEAFLET

Read all of this leaflet carefully before you take this medicine because it contains important information you need to know.

This medicine is available without prescription, however, you still need to use this product carefully to get the best results from it. Keep this leaflet as you may need to read it again. Ask your pharmacist if you need more information or advice.

1. What is this medicine and what is it used for?

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. This type of treatment is called Nicotine Replacement Therapy (NRT).

Your lozenges are a stop smoking aid. They can reduce your urge to smoke by providing some of the nicotine previously inhaled from cigarettes and helps you resist cigarettes. Because the lozenges do not contain the tar or carbon monoxide of cigarette smoke, they do not have the health dangers of tobacco.

This pack contains lozenges which are for smokers who smoke their first cigarette more than 30 minutes after waking up.

If possible, when giving up smoking these lozenges should be used with a stop smoking behavioural support programme.

This product can be used to help:
- 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, these lozenges 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.

This product can be used during pregnancy and breastfeeding *(see Pregnancy and Breastfeeding 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 these lozenges can help you stop. Any risks or possible side effects 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://smokefree.nhs.uk

2. Is this medicine suitable for you?

Do not take this medicine if you:
- are **allergic** to nicotine or any of the other ingredients
- are a non-smoker
- are under 12 years of age. 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.

If you are in hospital because of a **heart attack, severe heart rhythm disturbances** or a **stroke -** you should try to quit smoking without using nicotine lozenges, unless your doctor tells you to use them - once you are discharged from hospital, you can use these lozenges as normal.

Please see your doctor or pharmacist before taking this medicine if you:
- have **heart or circulation** problems including **heart failure or stable angina** (episodes of chest discomfort that are usually predictable)
- have **high blood pressure**
- have occlusive **peripheral artery disease -** which is a narrowing of the blood vessels outside of your heart
- suffer from **phenylketonuria,** a rare inherited metabolic disorder

- have **serious liver** or **kidney** disease
- have a **stomach ulcer** or **duodenal ulcer**
- have **inflammation of the oesophagus** (oesophagitis), which is the tube leading from the mouth to the stomach
- have an uncontrolled, **overactive thyroid** gland
- 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 been diagnosed as having a **tumour of the adrenal glands** (phaeochromocytoma)
- have had **allergic reactions** (see also section 5 "Possible side effects").

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

Pregnancy and breastfeeding

If you are pregnant or planning to become pregnant

Smoking when you are pregnant is harmful to your 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 are breastfeeding

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

If you are breastfeeding, it is best if you stop smoking without 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 breastfeeding:
- Try to breastfeed just before you take the lozenge, when the nicotine levels in your body are at their lowest. That way, your baby gets as little nicotine as possible.

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.

Important information about some of the ingredients in this medicine:
Each lozenge contains about **15 mg of sodium** and the maximum daily dose of these lozenges (15 lozenges) contains 225 mg sodium. To be taken into consideration if you are on a controlled sodium diet.

Contains **aspartame (E951)** which is a source of phenylalanine. May be harmful for people with phenylketonuria.

Your lozenges are **sugar free.**

3. How to take this medicine

Adults and young people aged 12 years and over
Instructions for use of these lozenges 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 are having 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.

Important: These lozenges are suitable for smokers who have their first cigarette of the day more than 30 minutes after waking up.

How to take your lozenges:
- 1 lozenge should be placed in the side of the mouth and allowed to dissolve
- At intervals, the lozenge should be moved from one side of the mouth to the other; the action should be repeated for 20 to 30 minutes until the lozenge is completely dissolved
- The lozenge should not be chewed or swallowed whole
- Users should not eat or drink while a lozenge is in the mouth as this may reduce the absorption of nicotine
- Do not use more than one lozenge at a time and do not use more than 15 lozenges per day.

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 the lozenges according to the **3-step programme below**, which is designed to gradually reduce the number of lozenges you use.

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**

To help you stay smoke free over the next 12 weeks, take a lozenge in situations when you are strongly tempted to smoke. During this initial treatment period (weeks 1 to 6) use at least 9 lozenges a day.

If you find it difficult to give up these lozenges or if you are worried that you may start smoking again then speak to your doctor or pharmacist.

It is important you complete the step down programme in full. This is because urges to smoke and withdrawal symptoms can occur for weeks after stopping smoking. If you resume smoking you may want to talk to your doctor or pharmacist about how to get the best results from your lozenges.

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

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 these lozenges 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:
This product 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 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 sometimes feel a craving for a cigarette. You can use this product 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.

4. What should you do if you take too many lozenges?

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.

5. Possible side effects

Sometimes there can be some side effects from giving up smoking or using the lozenges. This medicine may cause **allergic reaction,** which involves swelling of the face, lips and throat (angioedema) or itchy skin rash (urticaria). If this happens to you contact your doctor immediately.

Common side effects are:
- coughing, sore throat, mouth irritation or difficulty swallowing, dry mouth/throat/lips, ulcers in/around mouth
- sleep disturbances, including insomnia, anxiety, irritability, dizziness, headache
- feeling sick (nausea), being sick (vomiting), diarrhoea, constipation, hiccups, belching, wind, feeling bloated
- increased appetite, heartburn and indigestion.

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

Occasionally an increased heart rate may be experienced. If this happens stop using the lozenges and tell your doctor.

Uncommon side effects are:
- nightmares, abnormal dreaming, poor quality sleep, tiredness, lack of energy, feeling unwell, restlessness, alertness
- breathing problems, shortness of breath, asthma or worsening asthma, chest pain, tight chest
- throat irritation, taste disturbance, mouth numbness or burning, bleeding gums, bad breath, toothache, jaw pain, thirst
- migraine, mood swings and anger
- rash, itchy skin, skin irritation, hot flushes
- stomach pains, stomach ulcer, hiatus hernia, changes in appetite, taste changes, increased saliva
- irregular heartbeat (palpitations)
- sneezing, nasal congestion, catarrh, nasal discomfort, nose bleed
- increased sweating, sensory disturbance
- urgency to pass water at night
- painful and swollen legs.

If any of the side effects gets serious, or if you notice side effects not listed in this leaflet, please tell your doctor or pharmacist.

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 the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard By reporting side effects you can help provide more information on the safety of this medicine.

6. How to store your medicine

Keep all medicines out of the reach and sight 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.

7. What is in this medicine?

Your cream / white circular compressed lozenge is embossed with L344 on one side and has an odour of peppermint.
The active ingredient is nicotine 2 mg in the form of a resin complex (nicotine resinate 13.33 mg).
The other ingredients are: mannitol (E421), magnesium stearate, sodium alginate, xanthan gum, potassium bicarbonate, sodium carbonate anhydrous, aspartame (E951) and peppermint flavour.

Your lozenges are available in pack sizes of 12, 36 and 72's, although not all pack sizes may be marketed.

8. Who makes this medicine?

The Marketing Authorisation holder and manufacturer is Wrafton Laboratories Limited, Wrafton, Braunton, Devon, EX33 2DL, UK.

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Perrigo® Quality Affordable Healthcare Products™ T: +44 (0) 1226 779911 www.perrigouk.co.uk	PRODUCT	Galpharm Nicotine Replace 1mg Lozenges		PROJECT	Mediseal Blister Line
	VERSION	2	HUB 10554	PROFILE	L167 v3
	DATE	17/08/16	COMPONENT B7E00H9J1	DIMENSIONS	140x420mm
	AMENDED BY	AL	PHARMACODE 1421	SUPPLIER	Wrafton
	PRINT COLOURS	BLACK	NON-PRINT COLOURS	CUTTER	