

F5J00H9J1

PL 12063/0069

Text Revised: June 2013.

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

8. Who makes this medicine?

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

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

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

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Galpharm Nicotine Replace 4mg 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 within 30 minutes of 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

If you are finding it difficult to stop using NRT from further courses of NRT.

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.

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 after 6 weeks, talk to a healthcare professional.

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.**

Once you have stopped smoking completely as soon as you feel able to. Follow the instructions above, under 'Stopping smoking straightaway'.

It is best to stop smoking completely as soon as you feel able to. Follow the instructions above, under 'Stopping smoking straightaway'.

Adults aged 18 years and over: This product can help you manage your cravings soon as you feel able to. Follow the instructions above, under 'Stopping smoking straightaway'.

Going without cigarettes for a short time 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'.

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.

Adults aged 18 years and over: This product can help you manage your cravings soon as you feel able to. Follow the instructions above, under 'Stopping smoking straightaway'.

It is always best to stop smoking completely,