5. Possible side effects

Sometimes there can be some side effects from giving up smoking or using the lozenges. This medicine may cause allergic reactions which involve 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, itching, ulcers in/around mouth
- sleep disturbances, including insomnia, anxiety, irritability, dizziness, headache
- feeling sick (nausea), being sick (vomiting), diarrhoea
- increased appetite, heartburn and indigestion.

None of the above side effects are serious, and if they occur you should not stop using the lozenges or if an accidental overdose occurs, please tell your doctor or pharmacist.

6. How to store your medicine

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

This medicine may cause occasional stomach pains, stomach ulcer, hiatus hernia, rash, itchy skin, skin irritation, hot flushes, throat irritation, taste disturbance, mouth ulcers and tell your doctor.

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, shortage of breath, asthma or worsening asthma, chest pain, tight chest
- thirst, irritation, taste disturbance, mouth numbness or burning, bleeding gums, bad breath, toothache, jaw pain, thirst
- migraine, mood swings and anger
- itchiness, skin irritation, hot flushes or aching,,numbness or burning, bleeding gums, bad breath, toothache, jaw pain, thirst
- high blood pressure, dizziness, fainting, angina
- loss of appetite, diarrhoea, feeling unwell, restlessness, alertness
- changes in appetite, taste changes, numbness or burning, bleeding gums, bad breath, toothache, jaw pain, thirst
- 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 help 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 support programme. This product can be used to help stop smoking straightaway (a quit attempt) or after a period of time without using the lozenges (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), whereas others (such as children) could be harmed by tobacco smoke or in places where smoking is prohibited (temporarily abstaining)
- develop cravings once you have stopped smoking.

Reducing the number of cigarettes smoked can increase the chances that you will go on to quit (28/36/36).

6. Possible side effects

If you have 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 information or advice.

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- develop cravings once you have stopped smoking.

Reducing the number of cigarettes smoked can increase the chances that you will go on to quit (28/36/36).
If you are breastfeeding, it is best if you stop smoking without using NRT. 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 to use NRT for at least 9 lozenges a day.
- If you are under 18 years old, you should only use NRT with the advice of a healthcare professional.

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**

- **Initial treatment period**
  - 1 lozenge every 1 to 2 hours

**STEP 2**

- **Step down treatment period**
  - 1 lozenge every 2 to 4 hours

**STEP 3**

- **Step down treatment period**
  - 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.

If 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 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.

If you are finding it difficult to stop using NRT 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 to 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, 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.

**Important information**

**Possible side effects**

You may experience side effects from using NRT. The most common side effects are in the mouth as this may reduce the absorption of nicotine.

- 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**

- Do not use more than one lozenge at a time
- 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

**Pharmacode Information**

- If you are pregnant or planning to become pregnant
- When you stop smoking your metabolism will adjust
- Other important information:
  - 3-step 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.
  - Adults aged 18 years and over:
  - As soon as you feel able to. Follow the instructions above, under ‘Stopping smoking straightaway’.
  - 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’.
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  - Once 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.

**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 within 30 minutes of waking.

**How to take your lozenges**

- A 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

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