

NICABATE Lozenges

2 mg and 4 mg Nicotine

CONSUMER MEDICINE INFORMATION

Please read this information before you start taking this medicine.

What is in this leaflet?

This leaflet answers some common questions about NICABATE Lozenges. It does not contain all the available information.

It does not take the place of talking to your pharmacist or doctor.

All medicines have risks and benefits. Your doctor or pharmacist has weighed the risks of you using NICABATE Lozenges against the benefits this medicine is expected to have for you.

If you have any concerns about using this medicine, ask your pharmacist or doctor.

Keep this information with the medicine. You may need to read it again.

What are NICABATE Lozenges used for?

NICABATE Lozenges are a stop smoking aid. They can help you stop smoking over a few months. You can also use them to help you stop smoking more gradually over a longer period of time.

They help you to give up smoking by replacing some of the nicotine you are used to getting from cigarettes. It is the nicotine in cigarettes that can make you physically addicted to them. This type of treatment is called Nicotine Replacement Therapy (NRT).

NICABATE Lozenges contain a nicotine resin and, when used, nicotine is released slowly from the resin and absorbed through the lining

of the mouth. This medicine can reduce your urge to smoke by providing some of the nicotine previously inhaled from cigarettes and helps you resist cigarettes. You may feel the following withdrawal symptoms when you stop smoking: anger, irritability, frustration; anxiety; difficulty concentrating; restlessness; increased appetite and or weight gain; insomnia; depression. The nicotine in NICABATE lozenges may help relieve some or many of these symptoms.

NICABATE Lozenges do not have the health dangers of tobacco because they do not contain the tar, carbon monoxide or other toxins present in cigarette smoke.

If possible, when giving up smoking, NICABATE Lozenges should be used with a stop smoking behavioural support programme such as Click2Quit stop smoking programme.

NICABATE 2 mg lozenges are suitable for smokers who have their first cigarette of the day more than 30 minutes after waking up.

NICABATE 4 mg lozenges are suitable for smokers who have their first cigarette of the day within 30 minutes of waking up.

Your pharmacist or doctor may have given you this medicine for another reason.

If you need more information ask your pharmacist or doctor.

Before you use NICABATE Lozenges

When you must not take it

You should not use NICABATE Lozenges if:

- You are allergic to nicotine or any of the ingredients listed at the end of this leaflet.
- You are a non-smoker.
- You are an occasional smoker.
- You suffer from phenylketonuria. The lozenge contains phenylalanine.
- You are under 12 years of age.

There are no health benefits to smoking. It is always better to give up smoking and using NRT can help. In general any possible side effects associated with NRT are far outweighed by the well established dangers of continuing to smoke.

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 NRT unless your doctor tells you to use it. Once you are discharged from hospital, you may use NRT in consultation with your doctor.

If you have diabetes you should monitor your blood sugar levels more often than usual when starting NICABATE Lozenges as you may find your insulin or other medication requirements alter.

If you have had allergic reactions that involve swelling of the lips, face and throat (angioedema) or itchy skin rash (urticaria), using NRT can sometimes trigger this type of reaction.

If you are pregnant or breastfeeding, it is best if you can give up smoking without the use of NRT. However, it is better to stop smoking using NRT than to continue smoking.

Do not use NICABATE Lozenges if you are under 12 years of age.

The levels of nicotine in NRT are suitable for people who are giving up smoking but not for children under 12. Children are more likely to be affected by nicotine and it could cause severe toxicity which can be fatal. Make sure you keep nicotine containing products out of the reach and sight of children at all times.

Do not use the medicine after the expiry date (EXP) printed on the pack. If you use it after the expiry date has passed, it may not work as well.

Do not use NICABATE Lozenges if the packaging is torn or shows signs of tampering.

Do not use this medicine to treat any other complaint unless your doctor or pharmacist says it is safe. Do not give this medicine to anyone else even if they have the same symptoms as you.

Before you start to use it

You must tell your pharmacist or doctor if:

- You have an uncontrolled, overactive thyroid gland. Nicotine may make your symptoms worse.
- You have a stomach or duodenal ulcer or inflammation of the oesophagus. Swallowing nicotine can make your symptoms worse. Some people have reported getting mouth ulcers. If your symptoms do get worse you should talk to your doctor and you might want to use a non-oral type of NRT such as patches.
- You have heart or circulation problems including heart failure or stable angina or high blood pressure.
- You have had a stroke.
- You have any serious liver or kidney disease. You may be more prone to side effects.
- You are a diabetic.

- You have been diagnosed as having a tumour of the adrenal glands (phaeochromocytoma). Nicotine may make your symptoms worse.
- You have any allergies to any other medicines.
- You are pregnant or intend to become pregnant.
- You are breastfeeding or planning to breastfeed.

If you have not told your pharmacist or doctor about any of the above, tell them before you use NICABATE Lozenges.

If you are pregnant or breastfeeding then you should try to quit smoking without the use of NICABATE Lozenges if possible. However it is better to stop smoking using NRT than to continue smoking.

If you are pregnant

Smoking during pregnancy has risks such as poor growth of your baby before birth, premature birth or still birth. Stopping smoking is the best way to improve both your health and that of your baby. The earlier you stop smoking, the better.

Ideally, if you are pregnant, you should stop smoking without using NRT. However, if you have tried and this hasn't worked, NRT may be recommended to help you stop smoking. This is because it is better for your developing baby than if you carry on smoking. The decision to use NRT should be made as early on in your pregnancy as possible and you should aim to use it for only 2-3 months. Remember, the most important thing is to stop smoking.

Products that are taken intermittently, such as lozenges or gum, are preferable to nicotine patches. However, patches may be preferred if you have nausea or sickness.

If you are breastfeeding

Tobacco smoke causes breathing difficulties and other problems in babies and children. If you need to use NRT to help you quit, the amount of nicotine your baby may

receive is much smaller and less harmful than breathing in second hand smoke. Do not use patches if you are breastfeeding. You should use NRT products that are taken intermittently (eg gum or lozenges rather than patches) and breastfeed just before you take the product. This allows as long a time as possible between NRT use and feeding and will help your baby to get the smallest amount of nicotine possible.

Using other medicines

Tell your pharmacist or doctor if you are using any other medicines, including any that you buy without a prescription from your pharmacy, supermarket or health food shop.

Stopping smoking, with or without nicotine replacement products such as NICABATE Lozenges, may alter the absorption of some medicines. The doses of the other medicines that you are using may need to be changed.

You should tell your pharmacist or doctor if you are using any other medicines including any of the following medicines:

- Caffeine
- Theophylline
- Some medicines used to treat depression.
- Dextropropoxyphene and pentazocine – medicines that may be used for pain relief.
- Insulin
- Some medicines used to treat mental disorders.
- Frusemide (fluid tablet)
- Medicines used to treat ulcers.
- Blood pressure medicines

These medicines may be affected by NICABATE Lozenges or affect how well NICABATE Lozenges work.

Your pharmacist or doctor can tell you what to do if you are using any of these medicines.

If you have not told your pharmacist or doctor about any of

these things, tell him/her before you take any NICABATE Lozenges.

Things to be careful of

Each lozenge contains 15 mg of sodium that should be taken into account by those who are on a low sodium diet.

How to use NICABATE Lozenges

During any attempt to give up smoking using NICABATE Lozenges, it is important that you make every effort to stop smoking completely. However, if you do smoke a cigarette while you are using NRT, you should continue your quit attempt. Talking to your pharmacist or doctor may help.

For some people, the use of more than one NRT product may help them to identify the combination most appropriate for their individual quit attempt.

NICABATE 2 mg lozenges are suitable for smokers who have their first cigarette of the day more than 30 minutes after waking up.

NICABATE 4 mg lozenges are suitable for smokers who have their first cigarette of the day within 30 minutes of waking up.

One lozenge should be placed in the mouth and be allowed to dissolve to be effective. From time to time the lozenge should be moved from one side of the mouth to the other. The lozenge should not be chewed, sucked or swallowed whole.

You should not eat or drink while a lozenge is in your mouth. Coffee, juices and fizzy drinks may reduce the absorption of nicotine and should not be taken while you are sucking a lozenge.

Dosage

For smokers who want to stop in a few months.

NICABATE Lozenges should be used according to the following schedule:

Adults (and young people aged over 12 years)

Weeks 1 to 6
1 lozenge every 1 to 2 hours

Weeks 7 to 9
1 lozenge every 2 to 4 hours

Weeks 10 to 12
1 lozenge every 4 to 8 hours

To help you stay smoke free over the next 12 weeks, take 1 lozenge in situations where you are strongly tempted to smoke.

Do not use more than 1 lozenge at a time and do not use more than 15 lozenges per day.

Adults aged 18 years and over should use at least 9 lozenges a day for the first 6 weeks.

For adult smokers who want to stop over several months.

Use a lozenge whenever you have a strong urge to smoke instead of smoking a cigarette.

When you have reduced the number of cigarettes you smoke each day to a level you feel you can quit completely then use the schedule in the section above for smokers who want to quit in a few months.

If you have not reduced the number of cigarettes you smoke each day after 6 weeks, then see your pharmacist or doctor.

Using Nicabate combination therapy

Combination therapy can be used by smokers who have been unsuccessful giving up smoking when they have used just one type of NRT.

If you want to use NICABATE Patches together with NICABATE 2 mg Soft Gum or 2 mg Lozenges, you should start with the 21 mg patch and you should use at least 4 pieces of gum or lozenges each day. Most people use 4 to 5 pieces a day. Do not use more than 12 pieces of gum or lozenges a day.

Do not use the 4 mg Soft Gum or 4 mg Lozenges together with the Patches.

If you are using NICABATE Patches together with Soft Gum or Lozenges, the combination treatment should be used for 12 weeks. After this time you should begin weaning yourself off NRT. You can do this by:

- 1 Using the 14 mg patch for 2 weeks and then the 7 mg patch for 2 weeks while continuing to take the same number of lozenges or pieces of gum you routinely use. Once you are not using any patches, you can gradually reduce the number of lozenges or pieces of gum until you are not using any.

OR

- 2 Stop using the 21 mg patch and then gradually reduce the number of lozenges or pieces of gum you are using.

How long to use it

Lozenges should not be used after 9 months. If you find it difficult to give up NICABATE Lozenges or you are worried that you may start smoking again then speak to your pharmacist or doctor.

To give you the best chance for success, it is important you complete the step down programme in full. This is because the urge to smoke and withdrawal symptoms can occur for weeks after stopping smoking.

Young people aged 12 to 17 years old should only use NICABATE Lozenges for 12 weeks in total. If

you think you may need to use the lozenges for longer than 12 weeks, talk to your pharmacist or doctor. NRT should only be used by those aged 12 to 17 years if a counselling programme is used at the same time. NRT is not likely to work in this age group if there is no counselling with it.

Children under 12 years of age should not use NICABATE Lozenges.

If you do start smoking again, you may want to talk to your pharmacist about how to get the best results from further courses of NICABATE Lozenges.

The directions given to you by your pharmacist or doctor may be different from the information in this leaflet. If you are unsure how to use this medicine, ask your pharmacist or doctor for advice.

If you use too much (Overdose)

If you smoke or use any other nicotine containing product while you are using NICABATE Lozenges, you may suffer an overdose of nicotine. However if used correctly, nicotine overdose is unlikely.

Symptoms of nicotine overdosage include:

- Headache
- Dizziness
- Stomach upset
- Drooling
- Vomiting
- Diarrhoea
- Cold sweat
- Blurred vision
- Hearing distortion
- Confusion
- Weakness
- Fainting

If it is a large overdose, there may be collapse and breathing difficulty.

Immediately telephone your doctor or Poisons Information Centre

(telephone 13 11 26) for advice or go to Accident and Emergency at your nearest hospital, if you think that you or anyone else may have used too many NICABATE Lozenges.

Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention. Keep telephone numbers of these places handy.

The lozenges are not suitable for children under 12 or for non-smokers. They may develop signs of nicotine overdose including headache, sickness, stomach pains and diarrhoea. Even small amounts of nicotine can be dangerous to children. If you think a child has used any lozenges, you must contact a doctor immediately.

While you are using NICABATE Lozenges

Things you must do

Use NICABATE Lozenges exactly as your pharmacist or doctor has told you to.

Tell all your doctors, dentists and pharmacists that you are using NICABATE Lozenges.

Tell your doctor or pharmacist if you become pregnant while using NICABATE Lozenges.

Side Effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while taking NICABATE Lozenges.

NICABATE Lozenges help most people but they may have unwanted side effects in a few people.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need

medical treatment if you get some of the side effects.

Stopping smoking itself can cause some symptoms such as dizziness, headache, sleep disturbance, cough and cold-like symptoms. Symptoms such as depression, irritability, anxiety and insomnia may also be related to withdrawal symptoms associated with giving up smoking.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your pharmacist or doctor if you notice any of the following and they worry you:

- Sore throat, mouth irritation
- Nausea
- Hiccups
- Stomach upsets
- Vomiting
- Diarrhoea
- Excess saliva
- Dizziness
- Headache

These are the more common side effects of NICABATE Lozenges. Mostly these are mild and short-lived. You may experience these side effects as you decrease the number of lozenges that you use.

Tell your doctor immediately if you notice any of the following:

- Changes from your normal heartbeat
- Mouth ulcer
- Red or itchy skin

These may be serious side effects of NICABATE Lozenges. These side effects are uncommon.

If any of the following happen, stop using NICABATE Lozenges and tell your doctor immediately or go to accident and emergency at your nearest hospital:

- Fast or very irregular heartbeat
- Swelling of the face, lips, mouth or throat which may cause difficulty in swallowing or breathing. You may have a

serious allergic reaction to the medicine.

These are very serious side effects. You may need urgent medical attention or hospitalisation. These side effects are very rare.

Other side effects not listed above may also occur in some people. Tell your pharmacist or doctor if you notice anything else that is making you feel unwell. Do not be alarmed by this list of possible side effects. You may not experience any of them.

Transferred dependence

Some people worry that they will quit smoking but become dependent on nicotine lozenges. This is very rare and, if it did happen, it is less harmful to you than continuing to smoke and an easier habit to break.

After using NICABATE Lozenges

Storage

Keep your lozenges in the blister pack until it is time to use them.

If you keep the lozenges out of the carton or the blister pack they will not keep well.

Keep NICABATE Lozenges in a cool dry place where the temperature stays below 25°C.

Heat and dampness can destroy some medicines. Do not leave NICABATE Lozenges in the car on hot days.

Do not store NICABATE Lozenges or any other medicine in the bathroom or near a sink.

Keep NICABATE Lozenges where children and pets cannot reach them. A locked cupboard at least one and a half metres above the ground is a good place to store medicines.

Disposal

If your pharmacist or doctor tells you to stop using the lozenges, ask your pharmacist what to do with any lozenges that are left over.

This is not all the information that is available on NICABATE Lozenges. If you have any more questions or are not sure about anything, ask your pharmacist or doctor.

Product Description

NICABATE Lozenges come in two flavours, original and mint and in two strengths.

Active ingredient

Each lozenge or mint lozenge contains either 2 mg or 4 mg nicotine.

Other ingredients:

- Mannitol
- Sodium alginate
- Xanthan gum
- Potassium bicarbonate
- Calcium polycarboxylate
- Sodium carbonate anhydrous
- Aspartame
- Magnesium stearate

NICABATE Lozenges also contain menthol mint flavour.

NICABATE Mint Lozenges also contain mint flavour.

Supplied by

GlaxoSmithKline Consumer Healthcare
82 Hughes Avenue
ERMINGTON NSW 2115
ACN: 008 399 415

NICABATE Lozenges have the following Australian Registration numbers:

- AUST R 81977 (2 mg)
- AUST R 81978 (4 mg)

NICABATE Mint Lozenges have the following Australian Registration numbers:

- AUST R 106869 (2 mg)
- AUST R 106872 (4 mg)

Date of preparation: August 2008.

* Registered trade mark of the GlaxoSmithKline group of companies

NICABATE Click2Quit Free Personalised Stop Smoking Programme

Stopping smoking is a major decision that marks a turning point in your life. We are pleased that you have chosen to use NICABATE to help you quit.

Becoming an ex-smoker is not just about overcoming the cravings and urges for a cigarette, it is also about modifying your lifestyle to overcome the habits of smoking, like having a cigarette with your coffee or on the phone.

With NICABATE you don't have to go it alone. Using NICABATE Lozenges will help you reduce the cravings for a cigarette and by joining the Click2Quit programme, you can also receive help with the behavioural aspects of quitting.

The Click2Quit programme is FREE to anyone who has bought NICABATE Patches or Lozenges. It is a personalised behavioural support programme designed to help you break the behavioural aspects of your smoking habit.

TO JOIN THE Click2Quit PROGRAMME, CALL

1800 555 113
(FREECALL 7 days, Australia only)