

NICABATE Soft Gum

2 mg and 4 mg Nicotine

Consumer Medicine Information

Please read this information before you start using this medicine.

What is in this leaflet

This leaflet answers some common questions about NICABATE Soft Gum. 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 pharmacist or doctor has weighed the risks of you using NICABATE Soft Gum against the benefits they expect it will have for you.

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

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

What is NICABATE Soft Gum used for

NICABATE Soft Gum is a mint flavoured stop smoking aid. It can help you stop smoking over a few months. You can also use it to help you stop smoking more gradually over a longer period of time.

It helps you 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).

It contains a nicotine resin. When it is chewed, nicotine is released slowly from the resin and is 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. This nicotine also relieves many of the withdrawal symptoms such as feeling ill or irritable and cravings that you may feel when you try to give up.

NICABATE Soft Gum does not have the health dangers of tobacco because it does not contain the tar, carbon monoxide or other toxins present in cigarette smoke.

If possible, when giving up smoking, NICABATE Soft Gum should be used with a stop smoking behavioural support programme.

NICABATE 2 mg Soft Gum is suitable for smokers who smoke less than 20 cigarettes a day.

NICABATE 4 mg Soft Gum is suitable for smokers who smoke more than 20 cigarettes a day.

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 Soft Gum

When you must not use it

Do not use NICABATE Soft Gum 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 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 Soft Gum 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 Soft Gum 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 and dispose of the gum carefully.

Do not use this 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 Soft Gum 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 hereditary fructose intolerance. Each piece of gum (1 dose) contains up to 156 mg of sorbitol. Sorbitol is unsuitable for those with hereditary fructose intolerance. It can also cause stomach upset and diarrhoea.
- You are on a low sodium diet. Each piece of gum contains 11.4 mg of sodium and the maximum daily dose of NICABATE Soft Gum (20 pieces of the 2 mg strength) contains 228 mg sodium. The maximum daily dose of the 4 mg strength (10 gums) contains 114 mg sodium. The maximum daily dose may be harmful if you are on a low sodium diet.
- 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 Soft Gum.

If you are pregnant or breastfeeding then you should try to quit smoking without the use of NICABATE Soft Gum 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 gum or lozenges 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 to 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 Soft Gum, 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.

Other medicines may be affected by NICABATE Soft Gum or affect how well NICABATE Soft Gum works.

Your pharmacist or doctor can advise 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 Soft Gum.

Things to be careful of

If you have false teeth that are poorly fitted or not clean you may have difficulty chewing the gum. If you experience this problem, another nicotine replacement product may be more suitable for you such as a patch or lozenge.

Chewing nicotine gum may loosen fillings or dental implants.

The butylated hydroxytoluene in this product may cause irritation to the mouth or to the skin around it.

How to use NICABATE Soft Gum

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

During any attempt to give up smoking using NICABATE Soft Gum, 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.

The method of chewing nicotine gum is not the same as for ordinary chewing gum.

You should chew it as follows:

1. Chew gum slowly until taste becomes strong (about 1 minute).
2. Rest gum against your cheek (about 1 minute).
3. Chew gum again when taste has faded.
 - Keep chewing like this for about half an hour.
 - When the gum has lost its strong taste, you should dispose of it carefully.

Chewing the gum continuously causes the nicotine to be released from the gum too quickly. When this happens, the nicotine tends to be swallowed instead of absorbed through the lining of your mouth. Swallowing the nicotine may irritate your throat, upset your stomach or give you hiccups.

You should not eat or drink while the gum is in your mouth as this may reduce the absorption of nicotine.

You should use the 2 mg strength gum if you smoke less than 20 cigarettes a day.

You should use the 4 mg strength gum if you smoke more than 20 cigarettes a day.

Dosage

For smokers who want to stop in a few months

NICABATE Soft Gum can be used according to the following schedule.

Adults (and young people aged over 12 years):

- **STEP 1**
 - Initial treatment period 12 weeks
 - Chew 1 piece whenever there is an urge to smoke. Use 8-12 pieces/day of the 2 mg strength or 8-10 pieces/day of the 4 mg strength.

- **STEP 2**
 - Step down treatment period 2 weeks
 - Gradually reduce gum use to 4-6 pieces/day.
- **STEP 3**
 - Step off treatment period 2 weeks
 - Use 1-3 pieces of gum/day.
 - Reduce to zero over 2 weeks.

To help you stay smoke free, use 1 piece of gum when you are strongly tempted to smoke.

Do not use more than one piece of gum at a time.

Do not use more than 20 pieces/day of the 2 mg strength or 10 pieces/day of the 4 mg strength.

For adult smokers who want to stop over several months.

Use a piece of gum 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.

If you still need to use the gum on a regular basis 6 months after the start of treatment and haven't started a permanent quit attempt, you should seek help and advice from your healthcare professional.

Using Nicabate combination therapy

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

Do not use combination therapy in young people aged 12 to 17 years.

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

Over a period of 3 months you should use the gum to relieve the cravings to smoke. After 3 months you should be able to reduce the use of the gum. You should try to use fewer pieces of gum each day. When you are using only one or two pieces per day, you should try to stop completely. However, you should remember that you might feel a sudden craving to smoke long after you've given up and you can use the gum again if this should happen.

Young people aged 12 to 17 years old should only use NICABATE Soft Gum for 10 weeks in total. You can start off using 8-12 (maximum 15) pieces of the 2 mg gum or 8-10 (maximum 10) pieces of the 4 mg gum a day. Once you have broken the habit of smoking, start to reduce the number of pieces of gum you use a day until you are only using 1 or 2, then stop completely. If you think you may need to use it for longer, 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 Soft Gum.

If you find it difficult to give up NICABATE Soft Gum or you are worried that you may start smoking again then speak to your pharmacist or doctor.

If you feel you need to use the gum for longer than 9 months, ask your pharmacist or doctor for advice.

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

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 use too many nicotine lozenges/gums you may start to feel sick, dizzy and unwell. Stop using the lozenges/gums and immediately

telephone your doctor, or the Poisons Information Centre (telephone 13 11 26) or go to accident and emergency at your nearest hospital if you think you or anyone else may have used too much NICABATE Soft Gum.

Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

The gum is 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, you must contact a doctor immediately.

While you are using NICABATE Soft Gum

During any attempt to give up smoking using NICABATE Soft Gum, it is important that you stop smoking completely. Smoking even one cigarette decreases your chances of success.

Things you must do

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

Tell all the doctors, dentists and pharmacists who are treating you that you are using NICABATE Soft Gum.

Side Effects

Tell your pharmacist or doctor as soon as possible if you do not feel well while you are using NICABATE Soft Gum.

NICABATE Soft Gum helps most people but it 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 disturbances, cough and cold like symptoms, depression, irritability and insomnia. You may also get more mouth ulcers than usual.

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

This medicine contains the sugar alcohols, sorbitol, mannitol and maltitol. These may all have a laxative effect or cause diarrhoea.

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
- Indigestion/heart burn
- Flatulence
- Constipation
- Dry mouth
- Insomnia
- Cough
- Excess saliva
- Jaw muscle ache
- Dizziness
- Headache

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

If you tend to suffer from indigestion, the 4 mg gum may cause mild indigestion or heartburn.

Chewing the gum more slowly or using the 2 mg strength will usually help.

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 Soft Gum. These side effects are uncommon.

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

- Fast or very irregular heartbeat
- Severe allergic reaction symptoms of which include sudden wheeziness or tightness of the chest, rash and feeling faint.

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 gum. 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 Soft Gum

Storage

Keep the gum in the blister pack inside the carton until you are ready to use it.

If you take the gum out of its blister pack, it may not keep well.

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

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

Do not leave it in the car on hot days.

Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.

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 gum or the gum has passed its expiry date, ask your pharmacist what to do with any gum that is left over.

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

Product Description

What it looks like

NICABATE Soft Gum comes in two strengths.

- The 2 mg strength is an off-white rectangular pillow-shaped gum.
- The 4 mg strength is a yellow rectangular pillow-shaped gum.

Both strengths come in cartons of 12, 24, 48 or 96 pieces of gum.

Ingredients

Each piece of gum contains either 2 mg or 4 mg nicotine in the form of a resin complex called nicotine polacrilex. Nicotine polacrilex is also known as nicotine resinate. Amount based on 20% nicotine resinate.

The gum also contains the following inactive ingredients:

- Chewing gum base
- Calcium carbonate
- Butylated hydroxytoluene
- Sorbitol
- Maltitol solution
- Glycerol

- Acesulfame potassium
- Mint flavour
- Mannitol
- Sodium carbonate anhydrous
- Sodium bicarbonate
- Carnauba wax
- Talc-purified
- Quinoline Yellow CI47005 (4 mg strength only)

NICABATE Soft Gum is mint flavoured and sugar-free.

Manufacturer/Supplier

NICABATE Soft Gum is supplied in Australia by:

GlaxoSmithKline Consumer Healthcare

82 Hughes Avenue
 Ermington NSW 2115
 ACN: 008 399 415

2 mg gum: AUST R 117055

4 mg gum: AUST R 117060

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NICABATE is a registered trade mark of the GlaxoSmithKline group of companies.

NICABATE FREE STOP SMOKING PROGRAMME

Stopping smoking is a major decision which 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 life-style 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 Soft Gum will help you reduce the cravings for a cigarette and by joining the Nicabate stop smoking programme, you can also receive help with the behavioural aspects of quitting.

The Nicabate stop smoking programme is free to anyone who has bought NICABATE Patches, Lozenges or Gum. It is a behavioural support programme designed to help you break the behavioural aspects of your smoking habit.

TO JOIN THE PROGRAMME go to www.nicabate.com.au.