

NICABATE[®] Strips Mint Oral Films

2.5 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 Strips. 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 Strips 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 Strips used for?

NICABATE Strips 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 Strips contain nicotine and, when used, nicotine is released from the strip as it dissolves and the nicotine 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. 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 Strips may help relieve some or many of these symptoms.

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

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 Strips

When you must not take it

You should not use NICABATE Strips 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 under 12 years of age.

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.

Do not use NICABATE Strips 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 Strips 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 Strips.

If you are pregnant or breastfeeding then you should try to quit smoking without the use of NICABATE Strips 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 **NICABATE Strips**, 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 **NICABATE Strips** 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.

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 Strips as you may find your insulin or other medication requirements alter.

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 Strips, may alter the absorption of some medicines. The doses of the other medicines that you are using may need to be changed.

Other medicines may be affected by NICABATE Strips or affect how well NICABATE Strips 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 Strips.

How to use NICABATE Strips

NICABATE Strips are for smokers who have their first cigarette more than 30 minutes after waking up.

Place one NICABATE Strip on the tongue. Close the mouth and press the tongue gently to the roof of the mouth until the NICABATE Strip dissolves (approximately 3 minutes). The NICABATE Strip should not be chewed or swallowed. Users should not eat or drink while a NICABATE Strip is in the mouth.

Adults (18 years and over)

For smokers who want to stop smoking abruptly

NICABATE Strips should be used according to the following schedule:

Weeks 1 to 6

1 NICABATE Strip every 1 to 2 hours

Weeks 7 to 9

1 NICABATE Strip every 2 to 4 hours

Weeks 10 to 12

1 NICABATE Strip every 4 to 8 hours

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

Do not use more than 1 NICABATE Strip at a time and do not use more than 15 NICABATE Strips per day.

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

During any attempt to give up smoking using NICABATE Strips, 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.

For adult smokers who want to stop over several months

Use a NICABATE Strip 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 smoking abruptly.

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 NICABATE Strips on a regular basis 6 months after the start of treatment and haven't started a quit attempt, you should seek help and advice from 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 Strips, you should start with the 21 mg patch and you should use at least 4 strips each day. Most people use 4 to 5 strips a day. Do not use more than 12 strips a day when using in addition to the patch.

If you are using NICABATE 21mg Patches together with NICABATE Strips, 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 use the same number of strips you routinely use. Once you are not using any patches, you can gradually reduce the number of strips until you are not using any.

OR

- 2 Stop using the 21 mg patch and then gradually reduce the number of strips you are using.

Use in adolescents (12-17 years)

Young people aged 12 to 17 years should only use Nicabate Strips for 10 weeks in total. If you think you may need to use the strips for longer than 10 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.

Use in children

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

How long to use it

Adults (over 18 years): If you stopped smoking before using the product and you are still using the NICABATE Strips after 9 months you should talk to your pharmacist or doctor for advice. If you find it difficult to give up NICABATE Strips 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 Strips for 10 weeks in total (see **Use in adolescents (12-17 years)** above).

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 Strips.

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 Strips, 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 Strips.

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.

Nicabate Strips 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 strips, you must contact a doctor immediately.

While you are using NICABATE Strips

Things you must do

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

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

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

Side Effects

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

NICABATE Strips 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 or swollen throat
- Slightly sore or irritated mouth or tongue
- Nausea
- Hiccups
- Stomach upsets
- indigestion/heartburn
- Vomiting
- Diarrhoea
- Flatulence
- Constipation
- Dry mouth
- Insomnia
- Cough
- Excess saliva
- Dizziness
- Headache
- Palpitations (feeling your heart beat)

These are the more common side effects of NICABATE Strips. Mostly these are mild and short-lived. You may experience these side effects as

you decrease the number of NICABATE Strips that you use.

If any of the following happen, stop using NICABATE Strips 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 replacement therapy. 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 Strips

Storage

Keep your NICABATE Strips in the sachet until it is time to use them.

If you keep the NICABATE Strips out of the carton or the sachet they will not keep well.

Keep NICABATE Strips in a cool dry place where the temperature stays below 30°C.

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

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

Keep NICABATE Strips 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 NICABATE Strips, ask your pharmacist what to do with any NICABATE Strips that are left over.

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

Product Description

NICABATE Strips contain 2.5mg of nicotine.

Other ingredients:

- Methacrylic acid copolymer
- Triethyl citrate
- Peppermint flavour
- Sucralose
- Sodium hydrogen carbonate

This product may contain residual traces of ethanol.

Supplied by

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

NICABATE Strips have the following Australian Registration numbers:

- AUST R 193259

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

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 Strips will help you reduce the cravings for a cigarette and by joining our free stop smoking programme you can also receive help with the behavioural aspects of quitting.

This programme is FREE to anyone who has bought NICABATE. It is a programme designed to help you break the behavioural aspects of your smoking habit.

To join the programme, go to www.nicabate.com.au