

NICABATE and NICABATE P

Transdermal Patch

7 mg/24 hour, 14 mg/24 hour and 21 mg/24 hour 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 Patches. 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 Patches 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 are NICABATE Patches used for?

NICABATE Patches *are tan or clear square patches for sticking on your skin. They are a stop smoking aid which helps 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 Patches provide a steady amount of nicotine to your body, generally at a level lower than from cigarettes. This nicotine relieves some of the unpleasant symptoms such as feeling ill or

irritable that smokers often feel when they try to give up.

The nicotine can also reduce your cravings for a cigarette and help you to resist the urge to smoke.

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

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

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.

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 Patches

When you must not use it

Do not use NICABATE patches 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. Children are more likely to be

affected by nicotine and it could cause severe toxicity which may be fatal.

- You have a skin condition or disease such as allergic eczema or dermatitis.

In addition, do not use Nicabate Pre-Quit patches if:

- You smoke less than 15 cigarettes a day.
- You have heart problems.
- You weigh less than 45 kg.

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 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.

Nicabate Patches should be removed prior to undergoing MRI procedures.

If you are not sure whether you should start taking this medicine, talk to your doctor or pharmacist.

Before you start to use it

You must tell your pharmacist or doctor if:

- You have an uncontrolled, overactive thyroid gland.

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Nicotine may make your symptoms worse.

- You have heart or circulation problems including heart failure or stable angina or high blood pressure or have had a stroke. **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.
- You have any serious liver or kidney disease. You may be more prone to side effects.
- You are a diabetic. If you have diabetes you should monitor your blood sugar levels more often than usual when starting NICABATE patches as you may find your insulin or other medication requirements alter.
- 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 such as an itchy skin rash or swelling of the lips, face and throat.
- **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 have not told your pharmacist or doctor about any of the above, tell them before you use NICABATE Patches or NICABATE PRE-QUIT Patches.

Tell your doctor if you are pregnant (or intend to become pregnant) or you are breastfeeding (or planning to breastfeed).

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.

NRT 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 going to use NICABATE Patches, make sure you remove the patches before going to bed.

If you are breastfeeding

Tobacco smoke causes breathing difficulties and other problems in babies and children. Ideally, if you are breastfeeding, you should try to stop smoking without using NRT. 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. NICABATE Patches should not be used while breastfeeding. You should use NRT products that are taken intermittently (eg gum or lozenges) and breastfeed just before you take the product. This helps 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 Patches, 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 Patches or affect how well NICABATE Patches work.

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 use nicotine patches.

How to use NICABATE Patches

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

These may differ from the information contained in this leaflet.

If you do not understand the instructions on the box, ask your doctor or pharmacist for help.

After your quit date it is important that you make every effort to stop smoking completely. However, if you do smoke a cigarette while you are using NICABATE Patches, you should continue your quit attempt. Talking to your pharmacist or doctor may help.

People who smoke 15 or more cigarettes a day who want to begin their quit attempt without giving up cigarettes immediately, can use NICABATE PRE-QUIT Patches in the first 2 weeks of a quit attempt. After the 2 week course is completed, NICABATE Patches may be used as described below

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In some cases, the use of more than one NRT product may help them to make a quit attempt successful (see Using Combination Therapy). People who have used NICABATE PRE-QUIT Patches could use combination therapy after the initial 2 week Pre-Quit course.

How to use

Follow all directions given to you by your doctor or pharmacist carefully. They may differ from the information contained in this leaflet.

NICABATE PRE-QUIT Patches

These 24 hour patches are for smokers who smoke 15 or more cigarettes a day and who choose to smoke while preparing to quit.

Adults

Patch to be applied once daily for the first 2 weeks of the quit attempt.

After 2 weeks, stop smoking and start on the treatment schedule with regular patches. (see NICABATE Patches below)

Adolescents

Adolescents should not quit with Nicabate Pre-Quit Therapy.

NICABATE Patches

Adults

NICABATE patches are designed to be worn for 24 hours and to be used as part of a 10-12 week nicotine replacement therapy step down programme.

For smokers who have 10 or more cigarettes a day, treatment should start with the NICABATE 21mg patch and consists of :

Firstly, 6 weeks on a patch delivering 21mg of nicotine over 24 hours.

Next, 2 weeks on a smaller patch delivering 14mg of nicotine over 24 hours.

Followed by, 2-4 weeks on a very small patch delivering 7mg of nicotine over 24 hours.

Commence use in the morning after a smoke-free night. (Shift workers may need to adjust the timing.)

Your pharmacist or doctor may vary this schedule, eg, for people who weigh less than 45 kgs or who smoke less than 10 cigarettes per day or suffer from heart problems to:

Firstly, 6 weeks on a patch delivering 14mg of nicotine over 24 hours.

Followed by, 2-4 weeks on a patch delivering 7mg of nicotine over 24 hours.

NOTE: The nicotine strength of the cigarettes you smoked does not normally influence the patch dosage needed.

Adolescents

Young people aged 12 to 17 years should only use NICABATE Patches for 12 weeks. Use as described above for adults.

If you think you may need to use them 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

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

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 Nicotine Replacement Therapy (NRT).

NICABATE Patches can be combined with NICABATE 2 mg Soft Gum, 2 mg Lozenges or 1.5 mg Mini 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, 4 mg Lozenges or 4mg Mini Lozenges together with the patches.

The combination treatment of 21 mg patch and gum or lozenge 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.

Adolescents.

Adolescents should not quit using combination Therapy'.

Smoking while using oral forms of NRT

If you are not able to stop smoking abruptly, you can use NICABATE Soft Gum, NICABATE Lozenges or NICABATE Mini Lozenges while you gradually reduce the number of cigarettes you smoke over several weeks.

How to apply the patch

Before you open the pouch choose an area of skin and make sure it is clean, dry and hairless. We recommend the upper body or arms. Areas where the skin creases should

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be avoided. Do not apply patch to skin that is red, broken or irritated. Wear only one patch at a time.

Cut or tear open the pouch at the top.

Remove the stiff, transparent protective cover (one half at a time) and apply the sticky surface to the prepared skin area.

When applying the patch, avoid touching eyes and nose.

Press the patch firmly onto the skin with palm of your hand and hold in place for 10 seconds, then wash hands well to remove any traces of nicotine.

Dispose of the transparent protective covers carefully, away from children or pets.

When replacing the NICABATE Patch, choose a new skin site. Do not apply to previously used skin site for approximately one week.

You can swim, bathe and shower for short periods with the patch on. It is best not to use soap on the patch or skin immediately surrounding the patch as the soap may increase nicotine absorption.

If the patch peels off you may use a strip of adhesive tape to secure it. The patch is effective as long as it is against your skin.

How long to use it

If you are using NICABATE PRE-QUIT Patch, use for 2 weeks whilst smoking. By the end of the two weeks you should stop smoking completely and start using the NICABATE Patches for the recommended 10-12 week step down programme.

The patches should not be used for longer than 4 months. However, intermittent use products such as

NICABATE Lozenges, Mini Lozenges or Soft Gum can be used for up to 9 months.

It is recommended you wear the patch for 24 hours for best effect. However, if you are experiencing vivid dreams, try taking the patch off at bedtime (after 16 hours) and putting a new one on when you get up the next day.

If you are pregnant remove the patch at bedtime and replace when you get up the next day. (see *Before you start to use*)

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

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 Patches.

While you are using NICABATE Patches

If you forget to change the patch at your usual time, simply change it when you remember and then change the patch at the usual time the following day.

Side Effects

Tell your pharmacist or doctor as soon as possible if you do not feel well while you are using NICABATE Patches or NICABATE PRE-QUIT Patches. Nicotine patches 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. You may also get more mouth ulcers than usual.

Do not be alarmed by the following list of side effects. You may not experience any of them.

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

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

- Nausea
- Stomach upsets
- Vomiting
- Diarrhoea
- Dizziness
- Headache
- Dry mouth
- Indigestion
- Constipation
- Sleep disturbances
- Tremors
- Nervousness
- Tiredness or weakness
- Increased sweating
- Joint and muscle pain
- Shortness of breath/difficulty breathing
- Sore throat
- Cough

The above list includes the more common side effects. Mostly these are mild and short-lived. You may also experience these side effects as you decrease the strength of the patches that you use.

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These patches may cause other unwanted side effects in some people. You may get a slight redness and itching, burning and tingling of the skin where a patch has been. This usually disappears within a day.'

Tell your doctor as soon as possible if you notice any of the following:

- Changes from your normal heartbeat.
- Severe red or itchy skin at the sticking site.
- Sensitivity of the skin to sunlight

The above list includes serious side effects that may require medical attention. Serious side effects are rare.

If any of the following happen, stop using NICABATE Patches or NICABATE PRE-QUIT Patches 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.

The above list includes 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.

Transferred dependence

Some people worry that they will quit smoking but become dependent on nicotine patches. 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.

If you use too much (Overdose)

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

If you use more than one patch at once you may start to feel sick, dizzy and unwell. Remove all patches and wash and dry the skin with water only (no soap).

If you have started your quit attempt with NICABATE PRE-QUIT Patches and experience symptoms as listed below you should discontinue smoking and if symptoms persist remove the patch.

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 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 many NICABATE Patches.

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

The patches 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.

In the event of a child applying or playing with a new or used patch contact a doctor or the Poisons Information Centre (telephone 13 11 26) immediately.

After using NICABATE Patches

Storage

STORE OUT OF THE REACH OF CHILDREN AND PETS (New and used NICABATE patches contain nicotine, which can be harmful). A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Keep the patch sealed in the pouch until needed.

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.

Disposal

If your pharmacist or doctor tells you to stop using the patches or the patches have passed their expiry date, ask your pharmacist what to do with any patches that are left over.

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Used patches should be folded in half and placed back in the pouch. Dispose of carefully. Do not flush down the toilet.

Product Description

NICABATE[®] is available in 2 forms of patch: Opaque Patch (NICABATE) and Clear Patch (NICABATE Clear).

Each type is available in 3 nicotine dosage strengths:

21mg per 24hr (Step 1), 14mg per 24hr (Step 2) and 7mg per 24hr (Step 3). All strengths are available as one week supply (7 patches per box). Both Opaque and Clear 21mg patches are also available as two week supply (14 patches per box).

In addition;

NICABATE PRE-QUIT is available in packs of 14 patches in a strength of 21 mg/24 hr. NICABATE PRE-QUIT Patch is available in clear only.

NICABATE P is available as a 21mg /24 hour opaque patch . It is available in a pack of 28 patches. NICABATE P is only available on the PBS.

The main components of the patch are:

- A supply of nicotine in a co-polymer base. Base contains ethylene vinyl acetate with ethylene dioleamide.
- A polyisobutylene adhesive layer to stick the patch to the skin.

A rate controlling membrane to control the delivery rate of nicotine to the skin which contains polyethylene

Only difference between the two patches is colour; one is tan and the other clear.

Manufacturer/Supplier

NICABATE Patches are supplied in Australia by:

GlaxoSmithKline
Consumer Healthcare,
82 Hughes Avenue,
Ermington NSW 2115
ACN 008 399 415

AUST R 80205 (NICABATE 21 mg/24hr.)
AUST R 80207 (NICABATE 14 mg/24 hr.)
AUST R 80206 (NICABATE 7 mg/24 hr.)
AUST R 81035 (NICABATE Clear 21 mg/24 hr.)
AUST R 81034 (NICABATE Clear 14 mg/24 hr.)
AUST R 81033 (NICABATE Clear 7 mg/24 hr.)
AUST R 151699 (NICABATE PRE-QUIT)
AUST R 171308 (NICABATE P 21mg/24hr.)

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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 Patches 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 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

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