

Amcal Nicotine Patches

Active ingredient(s): Nicotine 21mg/24 hours; 14mg/24 hours; 7mg/24 hours

Consumer Medicine Information (CMI)

This leaflet provides important information about using Amcal Nicotine Patches. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Amcal Nicotine Patches.**

Where to find information in this leaflet:

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1. Why am I using Amcal Nicotine Patches?

Amcal Nicotine Patches contains the active ingredient nicotine [either 21mg/24 hours; 14mg/24 hours or 7mg/24 hours]. Amcal Nicotine Patches can help you stop smoking over a few months. You probably know that smoking is a very difficult habit to break. There are two aspects to quitting smoking. The first is the psychological dependence on cigarettes. You may have smoked for many years and smoking has become a routine part of your life.

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

The other side is the physical addiction to nicotine. Cigarettes supply nicotine, and your body has become dependent on nicotine.

Amcal Nicotine Patches deliver nicotine into your bloodstream through your skin. Using Amcal Nicotine Patches will help to gradually reduce the amount of nicotine your body craves each day.

Counselling is available from various support groups. To get the best out of Amcal Nicotine Patches, we encourage you to enroll in one of these groups.

Amcal Nicotine Patches are not intended for short periods, e.g. plane trips or other times when you cannot

smoke. They are designed to help you quit smoking, not as a substitute for smoking.

Amcal Nicotine Patches work most effectively when you also have a strong personal commitment to stop smoking. You cannot rely on Amcal Nicotine Patches alone to break the smoking habit. Amcal Nicotine Patches help relieve many nicotine withdrawal symptoms and cravings (such as early morning cravings), which you would otherwise have when you stop smoking.

2. What should I know before I use Amcal Nicotine Patches?

Warnings

Do not use Amcal Nicotine Patches if:

- you are under 12 years old
- you are a non-smoker or occasional smoker
- you have a generalised skin disorder that may complicate patch therapy (e.g. generalised psoriasis or chronic dermatitis)
- you have an allergy to nicotine or to any component of the patch
- the expiry date printed on the carton or sachet has passed
- the packaging is torn or shows signs of tampering

If you are in hospital because of a heart attack, severe heart rhythm disorders 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 the hospital, you may use NRT in consultation with your doctor.

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.

Check with your doctor or pharmacist if you:

- you have had a recent heart attack or stroke
- you have angina (chest pain) that is not well controlled or is getting worse
- you have severe arrhythmia (irregular heartbeat)
- you have uncontrolled high blood pressure
- you have a history of epilepsy (fits)
- take any medicines for any other condition, including medicines that you buy without a prescription
- you are aged 12-17 years
- you are pregnant or breastfeeding
- you have severe high blood pressure
- you have other heart or blood vessel disease
- you have diabetes

- you have kidney or liver disease
- you have hyperthyroidism (an overactive thyroid)
- you have phaeochromocytoma (a tumour of the adrenal gland).

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor or pharmacist if you are pregnant or intend to become pregnant.

Ideally, you should try to stop smoking without using NRT. Nicotine in any form may cause harm to your unborn baby. However, if you have tried and this has not worked, NRT may be recommended to help you stop smoking.

Seek advice from your pharmacist or doctor before starting NRT. 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. NRT products that are used intermittently, such as Amcal Nicotine Gum, are preferable to nicotine patches. However, patches may be preferred if you have nausea or sickness. If you use Amcal Nicotine Patches, make sure you remove the patch before bed.

Talk to your doctor or pharmacist if you are breastfeeding or intend to breastfeed.

Nicotine is excreted in breast milk in quantities that may affect the child even in therapeutic doses. Like smoking, NRT should be avoided during breastfeeding. However, if you are unable to quit without the use of NRT, seek advice from your pharmacist or doctor before starting a program. Do not use Amcal Nicotine Patches if you are breastfeeding.

Intermittent NRT products such as Amcal Nicotine Gum may be used instead, and should be used immediately after breastfeeding, to ensure that the baby gets the smallest amount of nicotine possible from breast milk.

Take special care:

- If you have stomach or duodenal ulcers or inflamed oesophagus or gullet (the passage between the mouth and stomach) because nicotine replacement therapy can make your symptoms worse.
- When taking this medicine there is a risk of dependence.

Amcal Nicotine Patches contain aluminium: you should not wear Amcal Nicotine Patches during MRI (Magnetic Resonance Imaging) procedures.

3. What if I am taking other medicines?

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

Smoking cessation and/or Amcal Nicotine Patches may change the way that other medicines work and you may not get the benefit from one or both products; for example, some medicines used for treatment of asthma, diabetes, schizophrenia, Parkinson's disease, high blood pressure, gastric ulcer, strong pain or angina pectoris may need dose adjustment. Your doctor or pharmacist will be able to advise you if stopping smoking or NRT may affect the way these medicines work.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Amcal Nicotine Patches.

4. How do I use Amcal Nicotine Patches?

How much to take / use

- Follow the instructions provided with the medicine.
- Do not exceed the recommended dosage.

Amcal Nicotine Quit Now program

The Amcal Nicotine Quit Now program lasts for 9-12 weeks. One patch is used each day for the duration of the program. Each patch is worn for one full day (24 hours). As the program progresses, a lower strength (smaller size) patch is used as your body's desire for nicotine decreases. Amcal Nicotine Patches are available in three nicotine dosage strengths: Amcal Nicotine Patch Step 1 (21 mg/24 hours), Amcal Nicotine Patch Step 2 (14 mg/24 hours) and Amcal Nicotine Patch Step 3 (7 mg/24 hours). Your correct starting strength depends on how many cigarettes you usually smoke each day.

	Amcal Nicotine Patch Step 1	Amcal Nicotine Patch Step 2	Amcal Nicotine Patch Step 3
If you smoke 20 or more cigarettes a day	Stop smoking and start with Amcal Nicotine Patch Step 1 Patch. Use for 3-4 weeks.	Move to Amcal Nicotine Patch Step 2 Patch. Use for 3-4 weeks.	Move to Amcal Nicotine Patch Step 3 Patch. Use for 3-4 weeks.
If you smoke less than 20 cigarettes a day		Stop smoking and start with Amcal Nicotine Patch Step 2 Patch. Use for 6-8 weeks.	Move to Amcal Nicotine Patch Step 3 Patch. Use for 3-4 weeks.

If you smoke during your course of treatment, consult your doctor or pharmacist.

Amcal Nicotine Pre-Quit program

If you smoke 20 or more cigarettes per day and are not sure you are able to give them all up at once, Amcal

Nicotine Pre-Quit program may be suitable for you. This involves wearing Amcal Nicotine Patch Step 1 while gradually reducing the number of cigarettes you smoke over 2 weeks leading up to your quit date. After 2 weeks, stop smoking and start on the Amcal Nicotine Quit Now program. You may also use Combination Therapy after the initial 2 week Pre-Quit program.

Combination Therapy

If you have relapsed in the past or if you experience cravings while using a single form of NRT, you can combine the use of Amcal Nicotine Patches with Amcal Nicotine Gum 2 mg.

A combination of NRT types is more effective than either product alone in people who have been unable to quit smoking using a single NRT method, increasing your chances of successfully quitting.

When using Amcal Nicotine Patch Step 1, chew one piece of Amcal Nicotine Gum 2 mg if you experience cravings. Use at least four pieces of gum but not more than 12 pieces in a day. Continue for 12 weeks.

After 12 weeks, you can wean yourself off NRT by either of the following methods:

1. Stop use of Amcal Nicotine Patches and gradually reduce the number of gums used until they are no longer needed.
2.
 - a. Use Amcal Nicotine Patch Step 2 for 3-4 weeks, while using the same number of pieces of Amcal Nicotine Gum 2 mg in a day that you have routinely used.
 - b. Then use Amcal Nicotine Patch Step 3 for a further 3-4 weeks, while using the same number of pieces of Amcal Nicotine Gum 2 mg in a day that you have routinely used.
 - c. When Amcal Nicotine Patch use is no longer needed, gradually reduce the number of gums you use until you no longer need them.

Adolescents 12-17 years old

Do not use for longer than 12 weeks. If you think you need to use Amcal Nicotine Patches for longer than 12 weeks, talk to your doctor or pharmacist.

Adolescents should not quit using the Amcal Nicotine Pre-Quit program or Combination Therapy.

Do not use for children under 12 years old.

How to apply Amcal Nicotine Patches

1. Cut open the sachet along the dotted line.
2. Remove the protective liner from the sticky side of the patch.
3. Apply the Amcal Nicotine Patch to a clean, dry, non-hairy area of skin free from creams, lotions (including sunscreen products or insect repellents), ointments, oil or powder. Wash and clean the area thoroughly before application. After a warm bath or shower, wait until the skin is cool and dry before application of the patch (especially important in hot and humid weather, so as to maximise initial adhesion).
4. Do not shave the skin as this could cause irritation.

5. The skin should not be red, broken or inflamed in any way (this includes e.g. sunburn, rash, eczema).
6. You may use your chest, back, upper arm or hip. Try to avoid areas where your skin folds when you sit or move.
7. Place the sticky side of the patch onto the area of skin you have chosen and press firmly with the palm of your hand for at least 10-20 seconds. Then run your fingers around the edge, pressing firmly. Do not try to check if the patch has stuck by lifting the edge. This may make it come loose.
8. An area of the skin used for a patch should not be used again for a new patch for at least seven days.
9. Avoid areas with skinfolds or where the skin creases.
10. The patch should be applied immediately after opening sachet.
11. Once applied, do not remove and re-apply elsewhere as the patch will not re-adhere well.
12. When replacing Amcal Nicotine Patches after 24 hours, choose a different location for the new patch.
13. Remove the used patch, fold it in half, sticky side inwards. Discard the used patch carefully, keeping it out of reach of children or pets.
14. When applying the patch, avoid touching the eyes and nose.
15. When you have finished, always wash your hands with water only.

Additional information

- You can shower while wearing Amcal Nicotine Patches. However, avoid spraying the shower jet directly onto the patch.
- Do not use bath or shower products with oily ingredients, either before or after application of the patch, as this could affect patch adhesion.
- When swimming for a long period in the sea or pool, you have two options:
 - a. before swimming, remove the patch and immediately replace it on its packaging. You will be able to stick it back onto your dry skin later on.
 - b. cover the patch with a waterproof adhesive dressing for the entire time that you swim.
- Despite using all the precautionary measures noted in this leaflet, be aware that excessive sweating or oily skin can lead to poor patch adhesion. Very hot or humid conditions can also affect adhesion.
- If the patch should fall off, secure it back in place with a medicinal adhesive tape or apply a fresh patch and continue. Change the patch at the usual time the following day.
- It is best not to use soap on the patch or skin immediately surrounding the patch.
- If you forget to change the patch at the usual time, change it when you remember and then change the patch at the usual time the following day.

If you use too much Amcal Nicotine Patches

If you think that you have used too much Amcal Nicotine Patches, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

The signs and symptoms of nicotine overdose include sweating, nausea (feeling sick) salivation, vomiting, stomach upset, diarrhoea, headache, dizziness, reduced hearing, vision disturbances or general weakness. More serious nicotine poisoning may include the following symptoms: irregular heartbeat, breathing difficulties or an uncomfortable chest, prostration (completely exhausted and unable to move), cardiovascular collapse (possible heart attack or decreased blood pressure) or convulsions (its).

If overdose is suspected, remove the patch immediately, wash the area liberally with water (do not use soap) and dry. Depending on the severity of the symptoms, seek advice from your pharmacist, doctor or hospital casualty department.

You should do this even if there are no signs of discomfort or poisoning.

Children: It is very important to keep both used and unused Amcal Nicotine Patches out of the reach and sight of children. Doses of nicotine that are tolerated by adult smokers can cause severe poisoning in small children and can be fatal.

5. What should I know while using Amcal Nicotine Patches?

Things you should do

- Use Amcal Nicotine Patches exactly as instructed.
- If you follow these recommendations, you should get the full benefit of the Amcal Nicotine Patches program.

Tell your doctor or pharmacist if you continue to smoke while you are using Amcal Nicotine Patches.

Tell all the doctors, dentists and pharmacists who are treating you that you are using Amcal Nicotine Patches.

Things you should not do

- Do not wear more than one Amcal Nicotine Patch at a time.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how Amcal Nicotine Patches affects you.

There is no evidence of any risk associated with driving or operating machinery if Amcal Nicotine Patches are used according to the recommended dose but remember that smoking cessation itself can cause behavioural changes

Looking after your medicine

Keep the patch in the sachet pack inside the carton until you are ready to use it.

If you take the patch out of its sachet, it may not keep well.

Store the patches below 30°C.

Do not store the patch in the refrigerator, even in hot weather, as this could lead to a loss of adhesion.

Follow the instructions in the carton on how to take care of your medicine properly.

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

Do not leave it in the car or on windowsills.

Heat and dampness can destroy some medicines.

Keep it where young children cannot reach it.

A locked cupboard at least 1.5 meters above the ground is a good place to store medicines.

When to discard your medicine (as relevant)

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

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

Like all medicines Amcal Nicotine Patches can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions.

Very common /common /uncommon side effects

Very common side effects	What to do
Application site reactions: <ul style="list-style-type: none">• Itching• Redness• Oedema (swelling)• Burning sensation	Speak to your doctor or pharmacist if you have any of these less serious side effects and they worry you.
Common side effects	
Nervous system disorders: <ul style="list-style-type: none">• Headache• Nausea• Dizziness Psychiatric disorders: <ul style="list-style-type: none">• Abnormal dreams	

<ul style="list-style-type: none"> • Sleep disturbance • Agitation • Anxiety • Nervousness <p>Respiratory system disorders:</p> <ul style="list-style-type: none"> • Cough <p>Musculoskeletal and connective tissue disorders</p> <ul style="list-style-type: none"> • Muscle pain • Arthritis • Disorder in muscle coordination <p>Gastrointestinal:</p> <ul style="list-style-type: none"> • Nausea • Abdominal pain • Upset stomach 	<p>Common side effects are often mild and will wear off naturally and rapidly once you have removed the patch.</p>
<p>Uncommon side effects</p>	
<p>Psychiatric disorders:</p> <ul style="list-style-type: none"> • Disturbance in attention • Sleepiness • Dramatic mood swings • Irritability • Depressed mood • Confusional state <p>Nervous system disorders:</p> <ul style="list-style-type: none"> • Sensation of tingling and prickling • Blurred vision • Hot flushes • Excessive sweating <p>Gastrointestinal:</p> <ul style="list-style-type: none"> • Disturbed taste • Vomiting • Constipation • Diarrhoea • Flatulence • Dry mouth <p>Cardiac disorders:</p> <ul style="list-style-type: none"> • Palpitations (feeling of heartbeats) • High blood pressure <p>Respiratory system disorders:</p> <ul style="list-style-type: none"> • Upper respiratory tract infections <p>Musculoskeletal and connective tissue disorders</p> <ul style="list-style-type: none"> • Joint pain • Muscle cramp • Back pain • Weakness • Pain or discomfort 	

In the event of a severe skin reaction that persists, stop treatment and consult your doctor or pharmacist to and another form of NRT to help you quit smoking.

These effects are usually caused by not changing the site of application each day. Changing the site each day will allow any irritation to disappear naturally and cause you very little discomfort.

Mouth ulcers may be related to quitting smoking and not to your treatment.

Serious/rare side effects

Serious side effects	What to do
<p>Immune system disorders:</p> <ul style="list-style-type: none"> • Allergic reactions, including puffing of the skin • Swelling of the face and mouth • Difficulty breathing <p>Cardiac disorders:</p> <ul style="list-style-type: none"> • Low blood pressure <p>Neurological disorders:</p> <ul style="list-style-type: none"> • Seizures (fits) 	<p>Call your doctor straight away or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p>
<p>Rare side effects</p>	
<p>Nervous system disorders:</p> <ul style="list-style-type: none"> • Tremor <p>Cardiac disorders:</p> <ul style="list-style-type: none"> • Chest pain • Disturbance in heartbeat rhythm <p>Respiratory system disorders:</p> <ul style="list-style-type: none"> • Difficulty breathing <p>Skin and subcutaneous tissue disorder</p> <ul style="list-style-type: none"> • Skin discolouration • Inflamed blood vessels in the skin 	<p>If you experience any of these, remove the patch and call your doctor straight away or go straight to the Emergency Department at your nearest hospital.</p>

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Keep Amcal Nicotine Patches out of reach of children at all times.

Nicotine is a highly toxic substance and could be life threatening to children. Each Amcal Nicotine Patch is sealed in a child-resistant sachet. Please take particular care to dispose of the used patches carefully.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

7. Product details

This medicine is available over-the-counter without a doctor's prescription.

What Amcal Nicotine Patches contain

Active ingredient (main ingredient)	Nicotine
Other ingredients (inactive ingredients)	Coconut oil- fractionated, Duro-Tak 387-2516, Methacrylic acid copolymer

Do not take this medicine if you are allergic to any of these ingredients.

What Amcal Nicotine Patches look like

Amcal Nicotine Patches are available in three nicotine dosage strengths, each corresponding to a different patch size.

Amcal Nicotine Patch Step 1 (30 cm² patch) 52.5 mg nicotine patch (release rate 21 mg nicotine per 24 hours)

Amcal Nicotine Patch Step 2 (20 cm² patch) 35 mg nicotine patch (release rate 14 mg nicotine per 24 hours).

Amcal Nicotine Patch Step 3 (10 cm² patch) 17.5 mg nicotine patch (release rate 7 mg nicotine per 24 hours).

Who distributes Amcal Nicotine Patches



Available only from Amcal

Allied Master Chemists of Australia Limited

3 Myer Place

Rowville Vic 3178 Australia

www.amcal.com.au

AUSTRALIAN OWNED

Amcal Nicotine Patches are supplied in Australia by:

Perrigo Australia

Suite 7, Level 1, 13a Narabung Way

Belrose NSW 2085

Customer Service: 1800 805 546

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