

Consumer Medicine Information

Please read this leaflet before you start to use the patches.

Nicotinell - 24 Hour Rate Controlled Release Nicotine Patch – Transdermal Nicotine

What is in this leaflet

This leaflet answers some common questions about Nicotinell 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 will be able to advise you about the risks and benefits of using Nicotinell Patches.

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 Nicotinell Patches used for?

Nicotinell 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 sides to quitting smoking. The first is the psychological dependence on cigarettes. You have probably smoked for many years and smoking has become an important part of your life.

The other side is the physical addiction to nicotine. Cigarettes contain nicotine, and your body has become dependant on nicotine. The Nicotinell patch delivers nicotine into your bloodstream through your skin. Using Nicotinell will help to gradually reduce the amount of nicotine your body craves each day.

Counselling is available from various groups such as Quit For Life. To get the best out of Nicotinell, we encourage you to enrol in one of these groups.

Nicotinell is not intended for short periods, e.g. plane trips or other times when you cannot smoke. It is designed to help you quit smoking, not as a substitute for smoking.

Nicotinell works most effectively when you have a strong personal commitment to stop smoking. You cannot rely on Nicotinell alone to break the habit. Each nicotine patch helps relieve many nicotine withdrawal symptoms and cravings (such as early morning), which would otherwise have when you stop smoking.

Before you use Nicotinell Patches

When you must not use it

Do not use Nicotinell Patch if:

- you are under 12 years old
- you are a non-smoker
- you have a generalised skin disorder such as psoriasis or 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

There are no health benefits to smoking. It is always better to give up smoking and using Nicotinell can help. In general, any possible side effects associated with nicotine replacement therapy (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 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.

Before you start to use it

Talk to your doctor and ask for his/her advice before using Nicotinell Patch if:

- 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)

Talk to your doctor or pharmacist and ask for his/her advice before using Nicotinell Patch if:

- you have severe high blood pressure
- you have other heart or blood vessel disease
- you have diabetes
- you have kidney or liver problems
- you have hyperthyroidism (a disorder of the thyroid gland)
- you have pheochromocytoma (a tumour of the adrenal gland)
- you are pregnant or breast-feeding
- you are aged 12 to 17 years

If you require further advice, you should talk with your doctor or pharmacist.

Tell your doctor or pharmacist if you are taking any other medicines, including medicines that you buy without a prescription. Your doctor or pharmacist will be able to advise you if stopping smoking may affect the way these medicines work.

Driving or operating machinery.

There is no evidence of any risk associated with driving or operating machinery if Nicotinell Patch is used according to the recommended dose but remember that smoking cessation can cause behavioural changes.

If you are pregnant.

Ideally you should not use this program while you are pregnant, and you should stop smoking without using nicotine replacement therapy. Nicotine in any form may cause harm to your unborn baby. However, if you are unable to quit without the use of nicotine replacement therapy, seek advice from your pharmacist or doctor before starting a program. 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. Products that are taken intermittently, such as gum, are preferable to nicotine patches. However, patches may be preferred if you have nausea or sickness.

If you are breast-feeding.

Nicotine is excreted in breast milk in quantities that may affect the child even in therapeutic doses. Like smoking, nicotine replacement therapy should be avoided during breast-feeding. However, if you are unable to quit without the use of nicotine replacement therapy, seek advice from your pharmacist or doctor before starting a program. Do not use Nicotinell Patch if you are breast-feeding. Intermittent NRT products such as Nicotinell nicotine chewing gums may be used instead, and should be used immediately after breast-feeding, to ensure that the baby gets the smallest amount of nicotine possible.

Patch should be removed prior to undergoing any MRI (Magnetic Resonance Imaging) procedures.

How to use Nicotinell Patches

How to get started

It is probably best to nominate a specific day that you will stop smoking. It may be helpful to:

1. Try to choose a day when you will not be where others are smoking.
2. Choose a day with as little stress as possible.
3. Choose a day not too far in the future.

Tell your family and friends that you have set this target "quit day".

This is the day you take complete control of your habit and become a non-smoker.

Prepare to stop smoking by trying to reduce the number of cigarettes you smoke each day. You should stop smoking completely while using Nicotinell.

How much to use

The Nicotinell course lasts for 9 to 12 weeks and one patch is used each day for the duration of use. Each patch is worn for one day (24 hours). As your course progresses, the aim is to use a lower strength (smaller size) patch as your body's desire for nicotine decreases. Nicotinell Patches come in 3 nicotine dosage strengths, Nicotinell Step 1 (21mg/24 hours), Nicotinell Step 2 (14mg/24 hours) and Nicotinell Step 3 (7mg/24 hours). The correct strength for you to start on depends on how many cigarettes you smoke each day.

Instructions are provided below for each of the two programs. Program A is for people who smoke 20 or more cigarettes each day and Program B is for people who smoke less than 20 cigarettes each day. Choose the correct program for you.

If you have a previous medical condition your doctor may choose to vary the dosage as appropriate.

Choose the program that is right for you.

Program A: If you smoked more than 20 cigarettes each day

Weeks 1 - 4:

1. Stop cigarette smoking and use one Nicotinell Step 1 patch each day for 3 to 4 weeks.
2. After 3 to 4 weeks you should no longer be smoking cigarettes and can move on to Nicotinell Step 2. However if you are still smoking, consult your doctor or pharmacist.

Weeks 5 - 8:

3. Use one Nicotinell Step 2 patch each day for another 3 to 4 weeks.

Program	Weeks 1-4	Weeks 5-8	Weeks 9-12	End program
A. If you smoked more than 20 cigarettes a day	Use Nicotinell Step 1 Patch 21 mg	Move to Nicotinell Step 2 Patch 14 mg	Move to Nicotinell Step 3 Patch 7 mg	Congratulations! You have successfully become a non-smoker
B. If you smoked less than 20 cigarettes a day	Use Nicotinell Step 2 Patch 14 mg	Move to Nicotinell Step 3 Patch 7 mg	Continue with Nicotinell Step 3 Patch 7 mg	Congratulations! You have successfully become a non-smoker

4. After week 3, if you are still a non-smoker, you can move on to Nicotinell Step 3. But if you have smoked during weeks 5 – 8, consult your doctor or pharmacist.

Weeks 9 - 12:

5. Use one Nicotinell Step 3 patch each day for another 3 to 4 weeks.
6. After week 9 to 12 you should stop using the patches. You have become a non-smoker. Congratulations!

Program B: If you smoked less than 20 cigarettes each day

Weeks 1 - 4:

1. Stop cigarette smoking and use one Nicotinell Step 2 patch each day for 3 to 4 weeks.
2. After 3 to 4 weeks you should no longer be smoking cigarettes and can move on to Nicotinell Step 3. But if you are still smoking consult your doctor or pharmacist.

Weeks 5 - 12:

3. Use one Nicotinell Step 3 patch each day for 5 to 8 weeks.
4. If you have smoked during your course of treatment in weeks 5 – 8, please consult your doctor or pharmacist before proceeding further.
5. Similarly, if you have smoked during your course of treatment in weeks 9 – 12, please consult your doctor or pharmacist.
6. After week 9 to 12 you should stop using the patches. You have become a non-smoker. Congratulations!

Combination therapy

If you have relapsed in the past or if you experience cravings while using a single form of nicotine replacement therapy (NRT), you can combine the use of Nicotinell patch with Nicotinell chewing gum 2 mg.

The combination 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 Nicotinell Step 1 patch, chew one piece of Nicotinell chewing gum 2 mg if you get a craving. Use at least 4 pieces of gum and not more than 12 pieces in a day. Continue for 12 weeks.

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

1. Stop use of Nicotinell Patch and gradually reduce the number of gums used until they are no longer needed.

2. a. Use Nicotinell Step 2 patch for 3-4 weeks, while using the same number of pieces of Nicotinell chewing gum 2 mg in a day that you have routinely used.
b. Then use Nicotinell Step 3 for a further 3-4 weeks, while using the same number of pieces of Nicotinell chewing gum 2 mg in a day that you have routinely used.
c. When patch use is no longer needed, gradually reduce the number of gums you use until you no longer need them.

Children 12 to 17 years old

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

Do not use for children under 12 years.

How to use Nicotinell Patches

- Cut open the sachet along the dotted line. Keep the sachet for the future disposal of the patch.
- Remove the protective liner from the sticky side of the patch.
- Apply the Nicotinell 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).
- Do not shave the skin as this could cause irritation.
- The skin should not be broken or inflamed in any way (this includes e.g. sunburn, rash, eczema).
- You may use your chest, back, upper arm or hip. Try to avoid areas where your skin folds when you sit or exercise.
- 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 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.
- Once applied, do not remove and re-apply elsewhere as the patch will not re-adhere well
- When replacing the Nicotinell patch after 24 hours, choose a different location for the new patch.
- Remove the used patch, fold it in half, sticky side inwards, replace in the original sachet and discard of carefully, keeping it out of reach of children or pets.
- Do not flush down the toilet.

Additional Information

- You can swim, bath or shower with the patch on. However, wait at least one hour after you apply the patch before undertaking any sweaty or wet activity. This will help maximise patch adhesion.
- Do not use bath oils or shower gels with oily ingredients, either before or after application of the patch, as this could affect patch adhesion.
- 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.
- Do not smoke while using the patch – remember there is nicotine in your system for several hours after removing 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.
- It is recommended that you do not apply the patch to a previously used skin site for three days.
- You should wear no more than one Nicotinell patch at a time.
- Nicotinell Patches should not be used for periods longer than three months.

While you are using Nicotinell Patches

Things you must do

Use Nicotinell exactly as instructed.

If you follow these recommendations you should get the full benefit of this Nicotinell program.

Stop smoking completely while using Nicotinell.

You may have increased side effects if you continue to smoke while wearing the patch.

Tell your doctor or pharmacist if you continue to smoke while you are using Nicotinell.

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

Things you must not do

Do not stop using Nicotinell Patches suddenly.

You may get side effects similar to those you would get if you stopped smoking suddenly.

Side effects

The nicotine in Nicotinell Patches can cause reactions like those caused by smoking. These reactions include dizziness, headache, nausea (feeling sick) or sleep disturbances. These reactions are usually mild but tell your doctor or pharmacist if they worry you.

The patch can cause skin irritation. Using a different area of skin to apply the patch each day can reduce this. However, if you have severe redness, swelling, itching, burning sensation or blisters at the patch site, or a rash (e.g. itchy red rash or hives) you should remove the patch and tell your doctor immediately or go to the Accident & Emergency at your nearest hospital. This could be an allergic reaction to Nicotinell.

Keep Nicotinell Patches out of reach of children at all time

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

If you use too much (overdose)

If you smoke or use other products containing nicotine while wearing a Nicotinell patch, you may suffer an overdose of nicotine. However if used correctly, nicotine overdose is unlikely.

The signs and symptoms of nicotine overdosage include pallor, sweating, nausea, salivation, vomiting, stomach upset, diarrhoea, headache, dizziness, hearing and vision disturbances, tremor, confusion, weakness, fainting and breathing difficulties.

If overdosage 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.

Children: It is very important to keep both used and unused Nicotinell Patch out of the reach and sight of children, as doses of nicotine that are tolerated by adult smokers can cause severe poisoning in small children and can be fatal.

In the event of overdose or suspected overdose, seek immediate medical advice or contact a Poisons Information Centre (Australia 13 11 26, New Zealand 0800 764 766).

After use

Storage

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 patch in the refrigerator, even in hot weather, as this could lead to a loss of adhesion.

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 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 patch or you find that it has passed the expiry date, ask your pharmacist what to do with any patches that are left over.

Product description

Nicotinell is available in 3 nicotine dosage strengths, each corresponding to a different patch size.

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

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

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

For more information

Ask your pharmacist or doctor if you have any questions, or if you experience any difficulties before, during or after using Nicotinell Patches. Nicotinell Patches are supplied in Australia by:

Novartis Consumer Health Australasia Pty Ltd

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Australia

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