

NICORETTE® PATCH

Nicotine

Consumer Medicine Information

What is in this leaflet?

Please read this leaflet carefully before you start to use Nicorette Patch. This leaflet answers some common questions about the patch and Nicotine Replacement Treatment (also called NRT).

It does not contain all the available information or take the place of professional advice such as talking to your pharmacist or a counsellor experienced with helping smokers to quit.

All medicines have risks and benefits. You need to weigh the risks of using the Nicorette Patch against the benefits it will have for you.

Use the Nicorette Patch as instructed and follow the advice given in this leaflet.

If you have any concerns about taking this medicine, you can seek the professional advice of your pharmacist, or for medical inquiries call 1300 362 486.

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

What Nicorette Patch is used for

Nicorette Patch helps you to give up smoking by relieving the desire to smoke, and some of the unpleasant effects which smokers experience when they stop smoking.

To successfully become a non-smoker it is important to understand how Nicorette Patch works.

How Nicorette Patch works

Smokers have both a physical reliance on nicotine (i.e. the body becomes dependant on nicotine) and a psychological reliance on the smoking habit itself.

When you give up smoking, your body will miss the effects of nicotine and you will miss the habit of smoking.

Nicorette Patch helps you to tackle these two sides of the problem separately, instead of all at once.

It is your body's dependence on nicotine which causes withdrawal symptoms when you suddenly stop smoking.

Symptoms may include:

- irritability
- restlessness
- depression
- weight gain
- craving for cigarettes

Nicorette Patch is intended to ease such withdrawal symptoms by providing your body with nicotine. This leaves your mind free to concentrate on overcoming your psychological desire to smoke.

The Nicorette Patch has been designed to slowly allow nicotine to be absorbed through your skin. The amount of nicotine in the Nicorette Patch is sufficient to help overcome the withdrawal symptoms but is lower than the amount of nicotine which you get from smoking. Therefore, overcoming your reliance on the nicotine in Nicorette Patch is much easier than overcoming your dependence on the nicotine you get from smoking.

Nicorette Patch is intended to help you to give up smoking, but you will only be successful in becoming a non-smoker if you are determined to quit.

You will also need the support of others, your family, your friends, or any one of a number of "quit smoking" organisations.

You will need to plan your stop-smoking program. Do not be afraid to seek support or advice.

For the Nicorette programme to be effective you must not smoke at all while using Nicorette Patch.

Before using Nicorette Patch

When you must not use Nicorette Patch

Do not use Nicorette Patch if:

- **you are pregnant or intend to become pregnant**

There is medical evidence that nicotine in any form may be harmful to an unborn child. Therefore it is recommended that you do not use Nicorette if you are pregnant or intend to become pregnant.

- **you are breast feeding or intend to breast feed**

Nicotine passes freely into breast milk, and can affect the health of the baby. Therefore it is recommended that you do not use Nicorette if you are breast feeding or intend to breast feed.

- **you have heart disease such as palpitations (fast or irregular heart beats) or angina**
- **you have had a recent heart attack or a stroke**
- **you have long term skin disorders like psoriasis or dermatitis**
- **you are a non-smoker, or only smoke occasionally**
- **you are under 18 years old**

There is not enough information about the use of the nicotine patch in children.

- **you are allergic to nicotine or may be sensitive to the patch adhesive**

You should not use Nicorette Patches if the expiry date printed on the carton has passed or the packaging is torn or shows signs of tampering.

Do not give Nicorette Patch to anyone else to use without professional advice from a pharmacist.

Before you start to use Nicorette Patch

If you have any of the following, you should ask for your pharmacist's advice before using Nicorette Patch.

These medical conditions may need consideration by or discussion with your doctor or pharmacist. You and your doctor or pharmacist can then weigh up the risk of using Nicorette Patch against the benefits you will get if you stop smoking.

The medical conditions include:

- any type of heart disease, including: angina or recent heart attack
- high blood pressure
- any blood circulation disorder
- kidney disease
- stomach ulcer or pain
- hyperthyroidism (a disorder of the thyroid gland)
- diabetes
- phaeochromocytoma (a tumour of the adrenal gland)

Taking other medicines

If you are taking any other medicines, including medicines that you buy without a prescription, in a pharmacy, supermarket or health food shop, the way these medicines work may be affected once you stop smoking.

These medicines may include:

- paracetamol
- caffeine
- theophylline
- oxazepam
- oestrogens
- warfarin
- lignocaine
- insulin
- imipramine
- pentazocine

You may wish to seek professional advice from your doctor or a pharmacist before you start to use Nicorette Patch.

Using Nicorette Patch

Which strength of Nicorette Patch to use

There are three different strengths of Nicorette Patch. All are intended to be used for 16 hours (not overnight).

When you first start to use the Nicorette Patch you should use the highest strength. This is the 15 mg/16h Nicorette Patch.

You should use this strength patch daily for 12 weeks.

Then you should reduce the amount of nicotine you are using by changing the strength of the patch you use.

Use the next lower strength 10 mg/16h for two weeks, and then the lowest strength 5 mg/16h for two weeks.

By gradually lowering the dose of nicotine you will find it easier to manage without the patch.

How to use Nicorette Patch

Choose and prepare an area of skin.

Before you open the pouch choose an area of skin and make sure it is clean and dry.

Any area of the body could be used, but preferably hairless skin is best to stick the patch on. Some examples may be the upper thigh, hip, under the upper arm or the chest.

The patch should be placed on a different part of the body each day. This will help reduce skin irritation if one site is used all the time.

Each patch is sealed in a child-proof pouch. You will need a pair of scissors to cut the pouch open.

Cut along one edge of the pouch with the scissors and carefully remove the patch.

Be sure to handle the patch carefully as the nicotine on the sticky side could come off on your hands.

This can cause stinging and redness if it gets near your eyes or nose.

To apply the patch remove the clear plastic coating and press the sticky side onto the clean dry skin for about 10 seconds.

Run your finger around the edge of the patch to ensure it sticks properly.

If you apply the patch correctly you can shower, bathe or swim without worrying about it coming off.

You should apply a patch first thing in the morning and remove it before you go to bed.

The patch is not intended to be worn at night when you are sleeping.

How to dispose of a used patch

After removal fold the used patch in half with the sticky side inward. Place the folded patch inside the opened pouch or wrap it in a piece of aluminium foil.

The used patch should then be disposed of carefully where children or animals cannot get hold of it.

Important: Immediately after applying or removing a Nicorette patch wash and dry your hands thoroughly so that you cannot get any nicotine into your eyes or nose.

Do not use soap as this may increase absorption.

Storage

Do not use a patch if the pouch or patch are damaged.

Keep all the pouches in the box until immediately before use.

Store Nicorette Patch at temperatures below 25°C. Storage in a car in hot weather may cause damage to the patch.

KEEP NICORETTE PATCH OUT OF REACH OF CHILDREN.

Starting to use Nicorette Patch

Set a Stop Smoking Day so that you can plan to be ready. This allows you to:

- remove temptations (throw away cigarettes; hide ashtrays).
- juggle your social calendar (avoid tempting situations - parties etc. in the early stages).
- tell family and friends that you are going to quit smoking - ask for their support.

When your Stop Smoking Day arrives, stop smoking completely on that day and begin your Nicorette treatment.

When to stop using Nicorette Patch

It is recommended that you use the 15 mg/16h Nicorette Patch for 12 weeks to help you get over your psychological desire to smoke.

After 12 weeks, you should gradually reduce the amount of nicotine by changing the strength of patch you use over the next 4 weeks.

Use the next lower strength 10 mg/16h for two weeks, and then the lowest strength 5 mg/16h for two weeks.

This gradual reduction in the amount of nicotine will help your body get used to going without nicotine.

If you notice some symptoms you could use a lower strength patch for a little longer.

Don't be discouraged by this, it is all part of the smoking cessation process.

When you reach this stage you can call yourself an ex-smoker, but there is still the chance that you may lapse back to your smoking habit. If you feel you need to keep using the patch, use the lowest strength patch to prevent you from having symptoms.

But don't forget, while you are wearing a patch your body may still be dependant on nicotine.

The use of Nicorette Patch beyond one year is not recommended.

If you use too much (overdose)

Overdosage can occur if more than one Patch is used, or you smoke or chew nicotine containing gum while you are wearing a patch.

There is a small risk that young children may be poisoned with nicotine if they put a patch in their mouth or apply them (especially more than one) to their own skin.

Anyone who swallows a patch needs immediate medical attention.

Signs of overdose or poisoning include:

- nausea and vomiting,
- diarrhoea
- cold sweats
- headache
- dizziness
- disturbed hearing and vision
- mental confusion
- weakness, faintness and fatigue
- loss of consciousness
- weak, rapid or irregular pulse

In the event of yourself or someone else showing symptoms seek medical advice.

Immediately telephone your doctor or Poisons Information Centre (telephone 13 11 26) for advice or go to casualty at your nearest hospital.

You can also help by doing the following:

- remove all the nicotine patches
- flush the skin with water and dry it

Do not use soap as this may increase absorption

While using Nicorette Patch

Several points will help you to more easily achieve your goal of becoming a non-smoker.

Never think "Surely one cigarette can do no harm".

Any smoking while using Nicorette will totally defeat your purpose and may increase the risk of side effects.

Develop strategies to tackle high risk times, e.g. when drinking alcohol, on the phone, after a meal, during meetings.

Occupy your hands.

Reward yourself when you reach the milestone of 4 weeks, 8 weeks and 12 weeks smoke-free.

Side effects

Nicotine like all other medicines may cause unwanted side-effects in some people.

Seek medical advice from your doctor or pharmacist as soon as possible if you do not feel well while you are using Nicorette Patch.

If you get chest pain, irregular heart beat, or bad indigestion do not smoke or use Nicorette or other nicotine medicines and see your doctor as soon as possible.

Most of the undesirable effects reported by users of Nicorette occur during the first weeks after beginning treatment. Some are minor and temporary but others may need medical attention.

Seek professional advice if you are not sure.

You may notice the following:

- redness or itching of the skin where the patch has been
- tingling in fingers or toes
- redness of the skin and hives.
- dizziness
- headache

- indigestion or heartburn
- irritability
- sleep disturbances
- light headedness

These are not likely to be serious.

Some effects, such as irritability, sleep disturbances and light-headedness, may be withdrawal symptoms due to low nicotine levels.

Tingling feelings and hives are uncommon.

If any of these effects do not go away, or you have any other undesirable effects during use, tell your doctor or pharmacist.

REMEMBER - that Nicorette Patch is not intended as an alternative to smoking and that your aim is to overcome your need for nicotine by the end of the treatment period.

After using Nicorette Patch

When the Nicorette Patch is no longer needed dispose of it carefully where children or animals cannot get it.

Do not be tempted to smoke again.

Product description

What Nicorette Patches look like

Nicorette Patches are rectangular and beige-pink (skin-tone) in colour.

Each of the three strengths is a different size. The largest patch is the highest strength and contains the most nicotine.

Identification

Nicorette Patch can be identified by an Australian Register Number which is found on the carton:

5 mg/16h AUST R 46058

10 mg/16h AUST R 46059

15 mg/16h AUST R 46060

Ingredients

The active ingredient in Nicorette Patch is nicotine.

Excipients:

polyisobutylene, polybutene, n-hexane, polyester (nonwoven)

Where to go for further information

If you need further information on Nicorette Patch call 1300 362 486

Manufacturer and Supplier

Nicorette Patch is made in Sweden and supplied in Australia by:

Pharmacia & Upjohn Pty Limited
ACN 000 185 526
59 Kirby Street
RYDALMERE NSW 2116

This leaflet was prepared in June 1997.

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