

TRANSIDERM-NITRO®

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using Transiderm-Nitro?

Transiderm-Nitro contains the active ingredient glyceryl trinitrate. Transiderm-Nitro is used to prevent angina.

For more information, see Section [1. Why am I using Transiderm-Nitro?](#) in the full CMI.

2. What should I know before I use Transiderm-Nitro?

Do not use if you have ever had an allergic reaction to glyceryl trinitrate or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I use Transiderm-Nitro?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Transiderm-Nitro and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use Transiderm-Nitro?

- You will normally apply a patch once each day, usually in the morning.
- Your doctor will likely ask you to take the patch off for 8 to 12 hours out of every 24 hours.

More instructions can be found in Section [4. How do I use Transiderm-Nitro?](#) in the full CMI.

5. What should I know while using Transiderm-Nitro?

| | |
|------------------------------------|---|
| Things you should do | <ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are using Transiderm-Nitro.• Tell your doctor if you continue to have angina attacks or if they become more frequent or severe while you are using Transiderm Nitro.• If you become pregnant while taking Transiderm-Nitro, tell your doctor immediately. |
| Things you should not do | <ul style="list-style-type: none">• Do not use Transiderm-Nitro to relieve an attack of angina.• Do not give this medicine to anyone else, even if their condition seems similar to yours.• Do not take it to treat any other complaints unless your doctor tells you to. |
| Driving or using machines | <ul style="list-style-type: none">• Be careful driving, operating machinery or doing jobs that require you to be alert until you know how Transiderm-Nitro affects you.• This medicine may cause dizziness, fainting or blurred vision in some people, especially when you first start to use it or if the dose is increased. |
| Drinking alcohol | <ul style="list-style-type: none">• Be careful when drinking alcohol while you are using Transiderm Nitro.• Your blood pressure may drop, making you feel dizzy or faint. |
| Looking after your medicine | <ul style="list-style-type: none">• Keep your medicine in the original container until it is time to use it. |

For more information, see Section [5. What should I know while using Transiderm-Nitro?](#) in the full CMI.

6. Are there any side effects?

Tell your doctor if you notice any of the following and they worry you: headache, which usually goes away after taking a mild pain reliever such as paracetamol, dizziness or lightheadedness, sometimes accompanied by a fast heart beat, especially when getting up suddenly, itching or burning under the patch, reddening of the skin after the patch has been taken off, flushing of the face, nausea (feeling sick) or vomiting, palpitations: abnormal feeling of heart beat. **Tell your doctor immediately or go to Accident and Emergency at your nearest hospital if you notice any of the following:** signs of allergy such as rash, itching or hives on the skin; swelling of the face, lips, tongue or other parts of the body; shortness of breath, wheezing or troubled breathing, severe redness, swelling or blisters under the patch, chest pains that are not relieved by taking your usual medicine for treating an angina attack, severe dizziness or fainting, severe or persistent headache

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

TRANSIDERM-NITRO®

Active ingredient(s): *glyceryl trinitrate*

Consumer Medicine Information (CMI)

This leaflet provides important information about using Transiderm-Nitro. **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 Transiderm-Nitro.**

Where to find information in this leaflet:

- [1. Why am I using Transiderm-Nitro?](#)
- [2. What should I know before I use Transiderm-Nitro?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use Transiderm-Nitro?](#)
- [5. What should I know while using Transiderm-Nitro?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using Transiderm-Nitro?

Transiderm-Nitro contains the active ingredient glyceryl trinitrate. Transiderm-Nitro is an adhesive patch that delivers a medicine called glyceryl trinitrate through the skin and into the bloodstream. Transiderm-Nitro belongs to a group of medicines called nitrates. Nitrates work by widening blood vessels, letting more blood and oxygen reach the heart.

Transiderm-Nitro is used to prevent angina.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed it for another purpose.

2. What should I know before I use Transiderm-Nitro?

Warnings

Do not use Transiderm-Nitro if:

- you are allergic to glyceryl trinitrate, or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can use this medicine.
- you are allergic to any other medicine or food containing nitrates or nitrites.
Some of the symptoms of an allergic reaction may include shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body; rash, itching or hives on the skin.
- you have severe anaemia
- you have glaucoma or raised pressure in the eye from any cause
- you have increased pressure in the head from any cause (stroke, tumour, head injury)

- you have disease in the valves of your heart or inflammation of your heart
- it is after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

Do not use Transiderm-Nitro if you are taking Viagra or Levitra, medicines used for impotence in men.

If you use Viagra or Levitra together with Transiderm-Nitro, your blood pressure may fall to a dangerously low level.

Check with your doctor if you:

- have any other medical conditions, including:
 - recent heart attack, stroke or head injury
 - heart problems or a blood vessel disorder other than angina
 - low blood pressure
 - problems with your lungs
 - problems with your liver
- take any medicines for any other condition
- are allergic to any other medicines, foods, dyes or preservatives.

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 if you are pregnant or intend to become pregnant.

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

This medicine may affect your baby if you use it while you are pregnant or breast-feeding. Your doctor can discuss with you the risks and benefits involved.

Use in children

There is not enough information to recommend this medicine for children.

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.

Some medicines and Transiderm Nitro may interfere with each other. These include:

- Viagra or Levitra, medicines used for impotence in men
- other medicines for angina
- medicines for high blood pressure or heart problems
- diuretic medicines, also called water or fluid tablets

- some medicines used to treat depression called tricyclic antidepressants
- medicines for mental disorders
- dihydroergotamine, a medicine for migraine
- acetylsalicylic acid (aspirin)
- medicines used to treat inflammation called non-steroidal anti-inflammatory drugs (NSAIDs)

You may need to take different amounts of your medicines or to take different medicines while you are using Transiderm-Nitro. Your doctor and pharmacist have more information.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Transiderm-Nitro.

4. How do I use Transiderm-Nitro?

How much to use

- Your doctor may start your treatment with one Transiderm-Nitro 25 patch each day for several days and then change to the larger Transiderm Nitro 50 patch.
- The usual dose for most people is one Transiderm-Nitro 50 patch each day, although some people may need more or less.

When to use Transiderm-Nitro

- You will normally apply a patch once each day, usually in the morning.
- Your doctor will likely ask you to take the patch off for 8 to 12 hours out of every 24 hours (e.g. take it off at bedtime and put a new one on when you wake up in the morning). This "patch off" period may make the medicine more effective.

How to use Transiderm-Nitro

How to apply the patch

Follow these steps to apply a patch to your skin.

1. Choose an area of skin:

- The best place is your chest but you may use any area except below your knees or elbows.
- Choose an area of skin that has no sores, cuts or rashes.
- If the skin is very hairy, you can clip the hair (do not shave it) so that the patch sticks well and won't be hard to remove.
- Use a different area of skin each day. Wait several days before using the same area again.

2. Make sure the skin is clean, cool, dry and free from creams, lotions or oils:

- You may need to wash the area with soap and water and dry it completely.
- If your skin is very oily, you can use methylated spirits to clean it, then dry it completely.
- After a shower or bath, wait a few minutes before applying the patch to make sure your skin is completely cool and dry.

- You may use body lotion or bath oil after the patch has been applied.

3. Open the sachet that contains the patch:

- Tear open the sachet at the notch and remove the patch.
- Do not use scissors because you may accidentally cut the patch and the medicine may leak out.
- Any air bubbles on the patch are not important.

4. Remove the protective liner from the sticky side of the patch:

- Pick up the patch with the tab upwards and the white liner facing you.
- Firmly bend the tab forward with your thumb.
- Use both thumbs to peel off the protective liner, starting at the tab. Do not touch the sticky surface of the patch.
- Throw the liner away.

5. Apply the patch to the skin as soon as you have removed the liner:

- Press the sticky side of the patch to the area of skin you have chosen so that the tan coloured side is showing.
- Press the patch firmly in place with the palm of your hand for 10 to 20 seconds. The patch needs the pressure and heat of your hand to stick well.
- Check that the patch has stuck by running your finger around the edge. Do not try to lift the edge of the patch to see if it has stuck.

How to remove the patch

- Use the little tab to pull the patch away from your skin.
- Fold the old patch in half with the sticky side inwards.
- Throw the old patch away safely out of the reach of children. The patch still contains some leftover medicine that could harm a child.
- Remove any stickiness from the skin with soap and water or methylated spirits.

If the patch falls off

- Throw the patch away.
- Apply a new patch to a different area of clean, dry skin.
- Change the patch at the next time that you would normally change it.

Bathing, swimming, showering or exercising will usually not affect the patch if it has been correctly applied.

If the patch irritates your skin

- Check that water has not gotten under the patch. If it has, remove the patch and apply a new one to a different area.
- Try a less sensitive area, for example your upper arm.
- Use a new area of skin for each patch. Do not use the same area of skin for at least a week.
- You can use a mild cream on the sore area once the patch has been removed.

How long to use Transiderm-Nitro

- **Use Transiderm-Nitro for as long as your doctor tells you to.**
Otherwise, you may not get relief from your attacks of angina. Try not to miss any doses and use the medicine even if you feel well.
- **Do not stop using Transiderm Nitro suddenly.**
Stopping this medicine suddenly may bring on attacks of angina, especially if you have been using it for several weeks or more. If you want to stop using it, your doctor will tell you how to do it gradually (e.g. over 4 to 6 weeks) to avoid making your angina worse.

If you forget to use Transiderm-Nitro

Transiderm-Nitro should be used regularly at the same time each day. If you miss your dose at the usual time, apply the patch as soon as you remember, respecting any prescribed patch-off period and then go back to using it as you would normally.

If it is almost time for your next patch, skip the patch you missed and apply your next patch when you are meant to.

Do not take a double dose to make up for the dose you missed.

This may increase the chance of you getting an unwanted side effect.

If you have trouble remembering when to use your medicine, ask your pharmacist for some hints.

If you use too much Transiderm-Nitro

If you think that you have used too much Transiderm-Nitro, 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.

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

Some of the symptoms of an overdose may include fast heartbeat, dizziness, light-headedness or fainting, especially when you get up quickly from a sitting or lying position. This is because your blood pressure is too low.

5. What should I know while using Transiderm-Nitro?

Things you should do

- **Tell your doctor if you continue to have angina attacks or if they become more frequent or severe while you are using Transiderm Nitro. Keep a record of the number of attacks, when they happen and the possible cause (for example, during exercise or during the period when the patch is off).**
- This helps your doctor give you the best possible treatment.

- **If you become pregnant while taking Transiderm-Nitro, tell your doctor immediately.**
- Your doctor can discuss with you the risks of using it while you are pregnant.

Remind any doctor, dentist or pharmacist you visit that you are using Transiderm-Nitro.

Things you should not do

- **Do not use Transiderm-Nitro to relieve an attack of angina.**
- This medicine will not relieve an attack of angina once it has started. Your doctor will have given you other tablets or spray to use when you get attacks of angina.
- **Do not give this medicine to anyone else, even if their condition seems similar to yours.**
- **Do not take it to treat any other complaints unless your doctor tells you to.**

Things to be careful of

- **If you are using more than one patch, be careful to remember where you placed it and when you put it on.**
- Some people using Transiderm Nitro will be using other medicines that are also patches. Sometimes keeping track of these patches can be confusing. Be sure to pay particular attention to where you put each patch and what time each patch should be removed.
- **Be careful not to overdo physical activities when you start using Transiderm-Nitro.**
- You may feel better when you start using it, but you will need time to improve your physical fitness.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how Transiderm-Nitro affects you.

This medicine may cause dizziness, fainting or blurred vision in some people, especially when you first start to use it or if the dose is increased.

Drinking alcohol

Tell your doctor if you drink alcohol.

Your blood pressure may drop, making you feel dizzy or faint.

If this medicine makes you feel light-headed, dizzy or faint, be careful when getting up from a sitting or lying position.

You can usually prevent these symptoms by getting up slowly and flexing leg muscles and toes to get the blood flowing. When getting out of bed, dangle your legs over the side for a minute or two before standing up. Use extra care when exercising, driving or standing for long periods, especially in hot weather.

Looking after your medicine

- Keep your medicine in the original container until it is time to use it.
- Store it in a cool dry place but not in the freezer.

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

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where young children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

When to discard your medicine

Used patches still contain some glyceryl trinitrate that could harm a child.

- Fold used patches in half with the sticky side inwards.
- Dispose of the patches where children cannot reach them.

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?

All medicines 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.

If you are over 65 years old, you should be especially careful and report any side effects promptly to your doctor.

As people grow older, they are more likely to get side effects from medicines.

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

Less serious side effects

| Less serious side effects | What to do |
|--|--|
| <ul style="list-style-type: none">• headache, which usually goes away after taking a mild pain reliever such as paracetamol• dizziness or lightheadedness, sometimes accompanied by a fast heart beat, especially when getting up suddenly• itching or burning under the patch• reddening of the skin after the patch has been taken off• flushing of the face• nausea (feeling sick) or vomiting• palpitations: abnormal feeling of heart beat. | Speak to your doctor if you have any of these less serious side effects and they worry you. |

Serious side effects

| Serious side effects | What to do |
|---|---|
| <ul style="list-style-type: none">• signs of allergy such as rash, itching or hives on the skin; swelling of the face, lips, tongue or other parts of the body; shortness of breath, wheezing or troubled breathing• severe redness, swelling or blisters under the patch• chest pains that are not relieved by taking your usual medicine for treating an angina attack• severe dizziness or fainting• severe or persistent headache | 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. |

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.

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.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What Transiderm-Nitro contains

Transiderm-Nitro 25 patches contain 25 mg glyceryl trinitrate and have a contact surface of 10 square cm. that releases approximately 5 mg glyceryl trinitrate in 24 hours.

Transiderm-Nitro 50 patches contain 50 mg glyceryl trinitrate and have a contact surface of 20 square cm. that releases approximately 10 mg glyceryl trinitrate in 24 hours.

| | |
|---|---|
| Active ingredient (main ingredient) | glyceryl trinitrate |
| Other ingredients (inactive ingredients) | lactose dimethicone silica colloidal anhydrous ethylene va copolymer silicon medical adhesive |

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

What Transiderm-Nitro looks like

Transiderm-Nitro patches are made up of five layers:

- a waterproof tan coloured backing film
- a drug reservoir containing glyceryl trinitrate
- a membrane which controls the release of glyceryl trinitrate into the skin
- an adhesive (sticky) layer
- a white to off-white protective liner which is removed before using the patch.

Transiderm-Nitro 25 – tan coloured oval patch marked CG DOD. Available in cartons of 30 patches (AUST R 17107).

Transiderm-Nitro 50 – tan coloured oblong patch marked CG DPD. Available in cartons of 30 patches (AUST R 17105).

Who distributes Transiderm-Nitro

Sandoz Pty Ltd
100 Pacific Highway
North Sydney, NSW 2060
Australia
Tel 1800 726 369

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