

Transiderm-Nitro®

glyceryl trinitrate TRANSDERMAL DRUG DELIVERY SYSTEM SACHET

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Transiderm-Nitro.

The information in this leaflet was last updated on the date listed on the final page. More recent information on the medicine may be available.

You should ensure that you speak to your pharmacist or doctor to obtain the most up to date information on the medicine. You can also download the most up to date leaflet from www.novartis.com.au.

Those updates may contain important information about the medicine and its use of which you should be aware.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you using Transiderm-Nitro against the benefits they expect it will provide.

If you have any concerns about this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What Transiderm-Nitro is used for

Transiderm-Nitro is used to prevent angina. It 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.

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.

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

Before you use Transiderm-Nitro

When you must not use it

Do not use Transiderm-Nitro if you are allergic to:

- glyceryl trinitrate (the active ingredient) or any of the other ingredients of Transiderm-Nitro listed at the end of this leaflet
- 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.

Do not use Transiderm-Nitro if you have any of the following medical conditions:

- severe anaemia
- glaucoma or raised pressure in the eye from any cause

- increased pressure in the head from any cause (stroke, tumour, head injury)
- disease in the valves of your heart or inflammation of your heart

If you are not sure whether any of the above medical conditions apply to you, your doctor can advise you.

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.

Do not use Transiderm-Nitro after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

In that case, return it to your pharmacist.

Before you start to use it

Tell your doctor if you have any of the following medical conditions:

- 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

Your doctor may want to take special precautions if you have any of the above conditions.

Tell your doctor if you are pregnant or breast-feeding.

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.

Tell your doctor if you are allergic to any other medicines, foods, dyes or preservatives.

Your doctor will want to know if you are prone to allergies.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you buy without a prescription from a 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.

If you have not told your doctor about any of these things, tell him/her before you start using this medicine.

How to use Transiderm-Nitro

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

They may differ from the information contained in this leaflet.

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

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 it

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 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 it

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 it

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

Otherwise, 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.

Do not use a double dose to make up for the one that 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 (overdose)

Remove the patch. Immediately telephone your doctor or Poisons Information Centre (telephone 13 11 26), or go to Accident and Emergency at your nearest hospital, if you think that you or anyone else may have used too much Transiderm-Nitro. Do this even if there are no signs of discomfort or poisoning. Keep telephone numbers for these places handy.

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.

While you are using Transiderm-Nitro

Things you must 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.

You doctor can discuss with you the risks of using it while you are pregnant.

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are using Transiderm-Nitro.

Tell any other doctor, dentist or pharmacist who treats you that you are using Transiderm-Nitro.

Things you must 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 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.

Be careful when drinking alcohol while you are using Transiderm-Nitro.

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.

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.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are using Transiderm-Nitro.

All medicines can have side effects. Sometimes they are serious, but most of the time they are not. You may need medical treatment if you get some of the side effects.

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.

Do not be alarmed by these lists of possible side effects. You may not experience any of them.

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

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

Tell your doctor if you notice anything else that is making you feel unwell.

Some people may have other side effects not yet known or mentioned in this leaflet.

After using Transiderm-Nitro

Storage

- 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. Store below 30°C. Do not store Transiderm-Nitro or any other medicine in the bathroom or near a sink.
- Do not leave it in the car or on window sills.

Keep the patches where children cannot reach them.

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

Disposal

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

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

If your doctor tells you to stop using Transiderm-Nitro or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Product description

What it looks like

Transiderm-Nitro 25 is a tan coloured oval patch marked CG DOD; 30 patches per carton.

Transiderm-Nitro 50 is a tan coloured oblong patch marked CG DPD; 30 patches per carton.

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.

Ingredients

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.

The patches also contain:

- lactose
- dimethicone
- silica colloidal anhydrous
- ethylene va copolymer
- silicon medical adhesive

Sponsor

Transiderm-Nitro is supplied in Australia by:

NOVARTIS Pharmaceuticals
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ABN 18 004 244 160
54 Waterloo Road
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Telephone 1 800 671 203

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This leaflet was prepared in July 2019.

Australian Registration Number.

Transiderm-Nitro 25 AUST R 17107

Transiderm-Nitro 50 AUST R 17105

(CMI tdn300719c based on PI tdn300719i)