

Nitro-Dur®

Transdermal Patches

Glyceryl trinitrate

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Nitro-Dur.

It does not contain all of 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 Nitro-Dur against the benefits they expect it will have for you.

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

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

What Nitro-Dur is used for

The name of your medicine is Nitro-Dur. It contains the active ingredient glyceryl trinitrate.

Nitro-Dur is used to prevent angina, but is not for the relief of a sudden attack of angina.

Angina is a pain or uncomfortable feeling in the chest, often spreading to the arms or neck and sometimes to the shoulders and back. This may be caused by too little blood and oxygen getting to the heart.

The pain of angina is usually brought on by exercise or stress.

Nitro-Dur belongs to a group of medicines called nitrates. It works by widening blood vessels, letting more blood and oxygen reach the heart.

The patch allows a measured amount of the medicine to pass through the skin into the blood stream.

Your doctor, however, may have prescribed Nitro-Dur for another reason. Ask your doctor if you have any questions about why Nitro-Dur has been prescribed for you.

Nitro-Dur is not recommended for use in children as there have been no studies of its effects in children.

There is no evidence that Nitro-Dur is addictive.

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

Before you use Nitro-Dur

When you must not use it

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

- Nitro-Dur, glyceryl trinitrate or any of the ingredients listed at the end of this leaflet
- any medicine or food containing nitrates or nitrites.

Symptoms of an allergic reaction may include wheezing or shortness of breath; swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing; hives, itching or skin rash.

Do not use Nitro-Dur if you are:

- severely anaemic
- taking any medicines which contain sildenafil, tadalafil, or vardenafil for erectile dysfunction or pulmonary arterial hypotension
- taking a medicine called riociguat for chronic thromboembolic pulmonary hypertension or pulmonary arterial hypertension.

Do not use Nitro-Dur if the packaging is torn or shows signs of tampering.

Do not use Nitro-Dur after the expiry date printed on the pack has passed.

If you use this medicine after the expiry date has passed, it may not work (as well).

If you are not sure whether you should start using Nitro-Dur, contact your doctor.

Do not give Nitro-Dur to children.

The safety and effectiveness of Nitro-Dur have not been established in children.

Before you start to use it

You must tell your doctor if:

1. **you have any allergies to:**
 - any other medicines
 - any other substances, such as food, preservatives or dyes.
2. **you are pregnant or intend to become pregnant.**

Your doctor will discuss the risks and benefits of using Nitro-Dur during pregnancy.

3. **you are breast-feeding or plan to breast-feed.**
Your doctor will discuss the risks and benefits of using Nitro-Dur during breast-feeding.
4. **you have or have had any medical conditions, especially the following:**
 - low blood pressure
 - heart problems, such as heart failure, or heart attack
 - anaemia
 - lung disease
 - stroke.

Taking other medicines

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

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

- medicines which contain sildenafil, tadalafil, or vardenafil for erectile dysfunction or pulmonary arterial hypotension. You must not take any medicines which contain sildenafil, tadalafil, or vardenafil if you are using Nitro-Dur as it may cause severe lowering of blood pressure and serious problems.
- a medicine called riociguat for chronic thromboembolic pulmonary hypertension or pulmonary arterial hypertension. You must not take riociguat if you are using Nitro-Dur as it may cause severe lowering of blood pressure and serious problems.
- medicines for high blood pressure or heart problems.
- tricyclic antidepressants.
- medicines for mental disorders.
- migraine medicine.

These medicines may be affected by Nitro-Dur, or may affect how well it works. You may need to take different amounts of your medicine, or you may need to take different medicines. Your doctor will advise you.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while using Nitro-Dur.

How to use Nitro-Dur

Be sure to use Nitro-Dur exactly as your doctor or pharmacist has told you to.

Apply only one patch every 24 hours. The Nitro-Dur patch is normally worn for about 12 hours per day. After this time it should be removed. There is usually a break of approximately 12 hours before a new patch is applied.

Do not try to trim or cut the adhesive patch to adjust the dosage.

It is important that you do not miss a day of your Nitro-Dur Transdermal Patch therapy.

1. Application

- Select a clean, dry skin area with little or no hair. A recommended area for application is the outer upper arm or chest. Avoid placing the patch on areas below the waist or elbows, on skin folds, on scars, or on burned or irritated areas.
- Be sure to remove the previous patch before applying a new one.
- Wash and dry hands before applying.
- Hold the patch with brown lines facing you in an up and down position.
- Keep bending the side of the patch away from you, then toward you until you hear the "snap".
- Peel off one side of the plastic backing.
- Using the other half of the backing as a handle, apply the sticky side of the patch to the recommended area and smooth down.
- Fold back the remaining side of the patch. Take off the plastic back and smooth down well.

- Wash your hands thoroughly to remove any medicine.
It is important to use a different application site every day to avoid skin irritation. A suggested rotation is:

- Day 1 - upper right arm
- Day 2 - upper right chest
- Day 3 - upper left chest
- Day 4 - upper left arm - then repeat from Day 1

2. Removal

- Press down on the centre of the patch to raise its outer edge away from the skin.
- Grasp the edge gently and slowly peel the patch away from the skin.
- Discard the patch in an appropriate manner so that no one else is accidentally exposed to it.
- Wash skin area with soap and water where the patch was applied. Towel dry.
- Wash hands to remove any medicine.

3. How Often to Change the Patches

The patch is usually worn for 12 hours per day, followed by a break of approximately 12 hours before a new patch is applied.

Your doctor may ask you to wear it for a different length of time. Your doctor will instruct you as to the time of day or evening that you should apply the patch.

Be sure to remove the old patch before applying a fresh patch.

If you forget to use it:

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

Otherwise, apply the patch as soon as you remember, 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.

If you are not sure what to do, ask your doctor or pharmacist.

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

If you use too much (overdose):

Remove the patch or patches immediately.

Telephone your doctor or Poisons Information Centre (telephone 13 11 26) for advice, or go to Accident and Emergency at your nearest hospital, if you think that you or anyone else may have used too much Nitro-Dur. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention. Keep these telephone numbers handy.

Symptoms of too much Nitro-Dur may include dizziness, light-headedness, persistent throbbing headache or heart palpitations.

While you are using Nitro-Dur

Things you must do

Use Nitro-Dur exactly as your doctor has prescribed.

If you do not follow your doctor's instructions, you may not get relief from your angina.

Tell your doctor if you continue to have angina attacks or if they become more frequent while you are using Nitro-Dur.

If you take "under-the-tongue" glyceryl trinitrate tablets while you are wearing your Nitro-Dur patch, you should sit down before taking the "under-the-tongue" tablet.

Taking an "under-the-tongue" tablet may make you dizzy.

Tell your doctor if you get dizzy.

Your doctor may need to reduce your tablet dosage.

Tell all doctors, dentists and pharmacists who are treating you that you are using Nitro-Dur.

Tell your doctor or pharmacist that you are using Nitro-Dur if you are about to be started on any new medicines.

Things you must not do

Do not use it to treat any other complaints unless your doctor says to.

Do not give these medicines to anyone else, even if their symptoms seem similar to yours.

Things to be careful of

Be careful driving or operating machinery until you know how Nitro-Dur affects you.

Nitro-Dur may cause dizziness and fainting in some patients, especially when you first start to use it. Make sure you know how you react to Nitro-Dur before you drive a car, operate machinery, or do anything else that could be dangerous if this happens to you.

Be careful not to overdo physical activities when you first start using Nitro-Dur.

You may feel better when you start using it, but you will need time to improve your physical fitness.

Get up slowly when getting out of bed or standing up if you feel light-headed, dizzy or faint.

You may feel light-headed or dizzy when you begin to use Nitro-Dur or if the dose is increased. This is because your blood pressure is falling suddenly. Standing up slowly, especially when you get up from bed or chairs, will help your body get used to the change in position and blood pressure. The problem usually goes away after the first few days.

If you feel dizzy, sit or lie down.

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

If you drink alcohol while using Nitro-Dur your blood pressure may drop, making you feel dizzy or faint.

After you remove the Nitro-Dur patch, your skin may feel warm and dry and appear red. This is normal. The redness will disappear in a short time.

If the area feels dry, apply a soothing lotion.

The chance of skin irritation may be reduced by regularly changing where on your body you wear your patch.

Tell your doctor if you have any redness or rash that does not disappear.

You can have a shower or bath while wearing a Nitro-Dur Patch.

Side effects

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

Nitro-Dur helps most people with angina, but it may have unwanted effects in a few people.

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

Ask your doctor or pharmacist any questions you may have.

Tell your doctor if you notice any of the following and they worry you:

- headache
- occasional light-headedness
- facial flushes
- faintness
- dizziness
- fast heart beat

Some people may get other side effects while using Nitro-Dur.

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

After using Nitro-Dur

Storage

Keep your patches in the foil pouch until it is time to use them.

If you take the patch out of the foil pouch it may not keep well.

Keep Nitro-Dur in a cool dry place where it stays below 30°C.

Do not store Nitro-Dur in the fridge.

Do not store it, or any other medicine, in a bathroom or near a sink. Do not leave it in the car or on window sills.

Heat and dampness can destroy some medicines.

Keep the patches where young 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

If your doctor tells you to stop using Nitro-Dur, or the patches have passed their expiry date, ask your pharmacist what to do with any patches left over.

Product description

Nitro-Dur Transdermal Patch contains glyceryl trinitrate in the polymer-based adhesive of the patch.

Active Ingredient:

- Glyceryl Trinitrate

Other Ingredients:

- butylacrylate polymers
- melamine formaldehyde resin
- sodium polyacrylate
- purified water.

There are three strengths of Nitro-Dur:

1. Nitro-Dur 5 delivers 5 mg glyceryl trinitrate per 24 hours
2. Nitro-Dur 10 delivers 10 mg glyceryl trinitrate per 24 hours

3. Nitro-Dur 15 delivers 15 mg glyceryl trinitrate per 24 hours

Each pack contains 30 patches.

Australian Register Number

- Nitro-Dur 5: AUST R 52340
- Nitro-Dur 10: AUST R 50561
- Nitro-Dur 15: AUST R 50563

Supplier

Merck Sharp & Dohme (Australia) Pty Limited

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