

NITRODERM[®] TTS

Nitroglycerin transdermal patch (25 mg, 50 mg)

What is in this leaflet

1. What Nitroderm TTS is used for
2. How Nitroderm TTS works
3. Before you use Nitroderm TTS
4. How to use Nitroderm TTS
5. While you are using Nitroderm TTS
6. Side effects
7. Storage and Disposal of Nitroderm TTS
8. Product Description
9. Manufacturer and Product Registration Holder
10. Date of Revision

What Nitroderm TTS is used for

Nitroderm TTS belongs to a group of medicines called nitrates which widen the blood vessels. This medicine is used to prevent or reduce the frequency of angina attacks (chest pain or discomfort).

How Nitroderm TTS works

Nitroderm TTS works by widening the blood vessels, which makes it easier for the heart to do its work. It may also be used for other conditions as determined by your doctor.

If an angina attack has already started, you should use a fast-acting nitrate (sublingual tablets or spray) instead of Nitroderm TTS patches.

Before you use Nitroderm TTS

Follow all the doctor's instructions carefully. They may differ from the general information contained in this leaflet.

When you must not use it

- If you are allergic (hypersensitive) to nitroglycerin, to any excipient of Nitroderm TTS, or to nitrates or nitrites.
- If you suffer from a breakdown of the blood circulation with very low blood pressure, such as in shock.

- If you have increased intracranial pressure (an increase of pressure in the brain).
- If you suffer from a disease of the valves of the heart or an inflammatory disease of the heart.
- If you are currently taking a medicine to treat erectile dysfunction from the group of so-called phosphodiesterase type 5 inhibitors (e.g. sildenafil).

If any of these apply to you, tell your doctor without taking Nitroderm TTS.

Pregnancy and breast-feeding

There is little experience with the use of Nitroderm TTS in pregnant women.

You should tell your doctor if you are pregnant, or if you plan to become pregnant. Your doctor will discuss with you the potential risks of taking Nitroderm TTS during pregnancy.

It is not known whether nitroglycerin passes into the breast milk. You should tell your doctor if you are breast-feeding.

Before you start to use it

- If you have anaemia,
- If you have a lung disease,
- If you have a heart disease or blood vessel disorder other than angina,
- If you have recently had a heart attack, stroke or head injury.

If any of these apply to you, tell your doctor before taking Nitroderm TTS.

Before any surgery, hospital admission, emergency unit visit, or imaging procedure, inform your doctors and nurses that you are wearing a Nitroderm TTS patch which contains an aluminium layer.

Taking Nitroderm TTS with food and drink

Be careful when drinking alcohol as your blood pressure may fall more than usual.

Children and adolescents

Nitroderm TTS patches are not suitable for children.

Taking other medicines

Tell your doctor or pharmacist if you are taking or have recently taken any other medicines in addition to Nitroderm TTS, including any medicines you may have bought without a prescription.

It may be necessary to change your dose or, in some cases, to stop one of the medicines. It is especially important for your doctor to know if you are taking:

- medicines used to lower high blood pressure,
- medicines that widen blood vessels such as other nitrates and hydralazine,
- medicines used to treat depression or mood disturbances,
- medicines used to treat mental disorders (major tranquillisers),
- medicines used to treat migraine (dihydroergotamine),
- medicines used to treat erectile dysfunction (inhibitors of an enzyme called phosphodiesterase type 5, including sildenafil)

How to use Nitroderm TTS

Your doctor will determine which type of patch you should use (Nitroderm TTS 5 or 10) and how many patches you should apply depending on your individual needs. Your doctor will also tell you when and how often to change your patch. Follow your doctor's instructions carefully. Do not exceed the recommended dose.

How much to use

In general, treatment is started with the smallest size patch (Nitroderm TTS 5) and increased gradually. For most people one Nitroderm TTS 10 patch is sufficient. Do not use more than two Nitroderm TTS 10 patches at a time.

Your doctor may tell you to remove the patch for 8-12 hours out of every 24 hours, usually at night (called patch-off period). If you feel your medicine is not helping you, tell your doctor. Depending on how you respond to the treatment, your doctor may suggest a higher or lower dose.

When to use it

You should normally put on a new patch once a day, usually in the morning.

How to apply Nitroderm TTS

Choose any area of skin on your trunk or upper arm. The skin should not be inflamed, broken, or irritated. To help the patch stick, the skin should be clean, non-hairy, dry, and free of creams, lotions, oil, or powder. You should apply the patch to a different area of skin each day. Wait several days before using the same area again.

Opening the sachets

Each Nitroderm TTS patch is sealed in a separate sachet. The sticky surface is covered with a white plastic protective backing.



Tear open the sachet where marked. Remove the patch from the sachet. Carefully pick up the patch with the tab up and the white protective backing facing you.



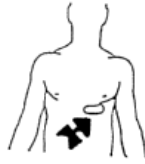
Removing the backing

Firmly bend the tab forward with your thumb. Peel off the white protective backing from the patch starting at the tab. Do not touch the sticky surface of the patch.

Applying the patch

Press the sticky side of the patch firmly to the area of skin you have chosen (e.g your trunk or upper arm) with the palm of your hand. Hold it there for about 10-20 seconds. Make sure that it sticks well, especially around the

edges. Do not test the patch by pulling it once it is on your skin.



When and how to remove the patch

Leave the patch in place on your skin for as long as the doctor told you. Peel it off and fold it in half, pressing the sticky sides together. Never cut or tear the patch.

Throw the old patch away, ensuring that it is out of the reach of children. Any adhesive left on the skin can be removed with alcohol. Stick a new patch on a different area of your skin.

Does it matter if the patch gets wet?

No. Bathing, swimming, showering, or exercising will not usually affect the patch if it has been correctly applied.

What to do if the patch falls off

It is not likely that a patch will fall off, but if it does, discard it and put on a new patch as soon as possible. You should put on your next patch at your regular time.

How long to use Nitroderm TTS

Continue using Nitroderm TTS for as long as your doctor recommends.

If you forget to use Nitroderm TTS

If you forget to change a Nitroderm TTS patch at the correct time, do not worry. Change it as soon as you remember, respecting any prescribed patch-off period. Apply the next patch at the correct time.

If you use too much (overdose)

If you have accidentally used more patches than your doctor prescribed, contact a doctor immediately. You may require medical attention.

While you are using Nitroderm TTS

Things you must do

Use your medicine exactly as your doctor has told you.

Things you must not do

If you have been using Nitroderm TTS regularly for several weeks or more, do not suddenly stop using it. Stopping suddenly may bring on attacks of angina. Your doctor will tell you the best way to stop treatment.

Things to be careful of

Driving and using machines

Nitroderm TTS may make you feel dizzy, especially at the start of treatment. You should therefore be careful when driving, using machines or doing other activities that require you to be alert.

Side effects

Like all medicines, Nitroderm TTS can have some side effects in some people. The following side effects may occur and may disappear during treatment. Usually they do not need medical attention, but check with your doctor if any of these last for more than a few days or are severe.

Very common side effects

Likely to affect 10 or more in every 100 patients

- Nausea
- Vomiting

Common side effects

Likely to affect between 1 and 10 in every 100 patients

- Headache, which may need treatment with a mild pain killer

Uncommon side effects

Likely to affect less than 1 in every 100 patients

- Irritation of the skin: The skin under the patch may become slightly red and itchy. This will disappear within a day after the patch is taken off.
- Skin allergies: The skin under the patch may become very red, swell, or form blisters. If

you develop a generalized rash, covering extensive areas of skin, it may be necessary to tell your doctor.

Rare side effects

Likely to affect between 1 and 10 in every 10'000 patients

- Reddening of the face
- Feeling dizzy when getting up quickly from a lying or sitting position due to low blood pressure. Getting up slowly may help. If you feel dizzy, sit or lie down.
- Fast heart beat

Very rare side effects

Likely to affect less than 1 in every 10'000 patients

- Dizziness

Other side effects

Number of patients affected cannot be calculated from available data

- Palpitations: abnormal feeling of heart beat. Contact your doctor if this affects you severely.

If any of these affects you severely, tell your doctor.

If you notice any other side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website portal.bpfk.gov.my (Consumers →Reporting).

Storage and disposal of Nitroderm TTS

Storage

- Do not use Nitroderm TTS after the expiry date shown on the box.
- Do not store above 25°C
- Store in the original package.
- Keep out of the reach and sight of children both before and after use.

Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how

to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

What it looks like

Nitroderm TTS patches are flat, foil patch, sealed at the edges, with white paste-like filling, one side with a greyish-orange backing film with imprint “CG DOD” for Nitroderm TTS 5 and “CG DPD” for Nitroderm TTS 10, the other side with an off-white protective liner. Oblong shaped with a tab on the longer side to peel off the protective liner.

Nitroderm TTS is an adhesive patch containing the active substance nitroglycerin, which is delivered through the skin into the bloodstream.

Ingredients

- *Active ingredient*

The active substance of Nitroderm TTS is nitroglycerin

- *Inactive ingredients*

The other ingredients are silica aerogel, silicone oil 360 for medical adhesive

MAL Number

Nitroderm TTS 5 (5MG/24HR):
MAL19870012AR

Nitroderm TTS 10 (10MG/24HR):
MAL19870013AR

Manufacturer

Novartis Pharma Stein AG, Stein, Switzerland.

Product Registration Holder

Novartis Corporation (Malaysia) Sdn. Bhd.
Level 22, Tower B, Plaza 33,
No. 1, Jalan Kemajuan,
Seksyen 13,
46200 Petaling Jaya

Date of revision

08/10/2015

Serial Number

BPFK(R4/1)140815/00249