

## Patient Information Leaflet

### **Transiderm-Nitro 5 milligrams/24 hours, Transiderm-Nitro 10 milligrams/ 24 hours and Transiderm-Nitro 15 milligrams/24 hours Transdermal patch (glyceryl trinitrate)**

**Read all of this leaflet carefully before you start using Transiderm-Nitro.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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#### **1. What Transiderm-Nitro is and what it is used for**

Transiderm-Nitro is a patch which you stick on your skin. The patch contains a supply of glyceryl trinitrate which is released from the patch and absorbed through the skin and into the blood vessels. This is called a transdermal patch.

Glyceryl trinitrate, the active ingredient in the patches is one of a group of medicines called vasodilators. These cause blood vessels to relax, increasing the supply of blood and oxygen to the heart and reducing the amount of work the heart has to do.

Transiderm-Nitro 5, 10 and 15 are used:

- to prevent angina attacks. Angina means a painful tightness in the chest. This is a good description of a typical attack, although the pain may also be felt in the arm or neck. The pain really comes from the heart muscle and is a sign that part of the muscle is not getting enough blood supply for the amount of work it has to do.

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

#### **2. Before you use Transiderm-Nitro**

##### **Do not use Transiderm-Nitro if:**

- you are allergic (hypersensitive) to glyceryl trinitrate or any of the other ingredients of Transiderm-Nitro (listed in Section 6 below)
- you have very low blood pressure
- you have headaches, vomiting or seizures as a result of raised intracranial pressure
- you have any problems with your heart because of faulty valves or inflammation
- if you are taking any medicines (e.g. sildenafil) for erectile dysfunction (male impotence)
- if the amount of blood in your body is severely reduced (hypovolaemia).

Do not use Transiderm-Nitro if any of the above applies to you. If you are not sure, talk to your doctor or pharmacist before using Transiderm-Nitro.

### **Take special care with Transiderm-Nitro**

Check with your doctor or pharmacist before using Transiderm-Nitro if:

- you have recently had a heart attack, suffer from heart failure or have any other heart problems
- you have anaemia or lung disease
- you are pregnant or trying to become pregnant
- you are breast-feeding
- you have recently had a stroke or head injury.

If any of the above apply to you (or you are not sure), talk to your doctor or pharmacist before using Transiderm-Nitro.

### **Taking other medicines**

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines. This includes medicines obtained without a prescription.

Transiderm-Nitro reacts with a large number of other medicines. In particular, do not take Transiderm-Nitro if you are taking the following:

- medicines for erectile dysfunction (male impotence). Do not take Transiderm-Nitro if this applies to you. If you are not sure, talk to your doctor or pharmacist before taking Transiderm-Nitro.

Tell your doctor or pharmacist if you are taking any of the following:

- medicines for depression
- ergotamine products which are usually given for migraine
- medicines for high blood pressure or heart problems
- aspirin (acetyl salicylic acid) or other painkillers called NSAIDs (non-steroidal anti-inflammatory drugs)
- diuretics (“water tablets”)
- tranquillisers (e.g. chlorpromazine, flupenthixol, haloperidol, clozapine)
- medicines that widen blood vessels such as other nitrates and hydralazine
- medicines used to treat mental disorders.
- amifostine – used to protect the body from some cancer treatments

If any of the above apply to you (or you are not sure), talk to your doctor or pharmacist before using Transiderm-Nitro.

### **Operations and tests**

Before any surgery, hospital visit, imaging procedure or heat therapy advise all doctors and nurses that you are wearing a Transiderm-Nitro patch which contains an aluminium layer.

### **Using Transiderm-Nitro with alcohol**

Be careful when drinking alcohol as the patch may affect you more than usual and you might feel faint or dizzy.

### **Pregnancy and breast-feeding**

Talk to your doctor before using Transiderm-Nitro if you are pregnant, might become pregnant or are breastfeeding.

### **Driving and using machines**

Do not drive or use machines if you feel dizzy or affected by Transiderm-Nitro. Transiderm-Nitro may make you feel dizzy or faint, especially at the start of treatment.

### **3. How to use Transiderm-Nitro**

It is important to follow what your doctor says about how and when to use your patches. The dose will be on the pharmacist's label. Check the label carefully. If you are not sure, ask your doctor or pharmacist.

#### **Using this medicine**

The usual dose for adults and the elderly is one or two patches a day. The doctor will have decided which strength of patch you need.

You may be told to wear a patch all of the time or for only part of the day. Don't forget to follow the doctor's instructions exactly.

Your doctor will tell you how often to change the patch. You should normally put on a new patch in the morning. Discard the old patch carefully because it will still contain a little of the active ingredient.

The side of the chest or upper arm are suitable places to apply the patch. Choose a different area of skin each time you apply a new patch. Leave several days before you use the same patch of skin again. More instructions on how to apply your patches are given at the end of this leaflet.

Sometimes patches are not enough to prevent all of your angina attacks and you may be given tablets as well. Make sure you know when you need to take the tablets.

#### **Transiderm-Nitro is not suitable for children.**

#### **If you use more Transiderm-Nitro patches than you should**

If you accidentally apply too many Transiderm-Nitro patches, tell your doctor or nearest hospital casualty department immediately. Take your medicine pack with you.

#### **If you forget to use Transiderm-Nitro**

If you forget to change your patch, do not worry. Put on a new one as soon as you remember. Then go on as before.

#### **If a patch falls off**

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

#### **If you stop using Transiderm-Nitro**

**Do not** stop using the patches suddenly without consulting your doctor first. Stopping suddenly may bring on attacks of angina. Your doctor will tell you the best way to stop treatment.

### **4. Possible side effects**

Transiderm-Nitro is suitable for most people. However, like all medicines it can cause side effects, although not everybody gets them.

#### **The side effects listed below have been reported:**

**Very common** (more than 1 in 10 people have experienced):

- nausea (feeling sick) or vomiting (being sick).

**Common** (up to 1 in 10 people have experienced):

- headaches. These will probably wear off after a few days. If necessary you can take mild painkillers e.g. paracetamol.

**Uncommon** (up to 1 in 100 people have experienced):

- reddening, itching or burning of the skin at the site of the patch. Be sure to put your patch in a different place each day
- allergic skin reactions such as reddening or itching anywhere on the body.

**Rare** (up to 1 in 1,000 people have experienced):

- increased heart rate or palpitations
- feeling faint or light-headed on standing
- flushing of the face.

**Very rare** (up to 1 in 10,000 people have experienced):

- dizziness.

**If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist. The doctor may want to reduce the dose or give you a different medicine.**

### **Reporting of side effects**

**If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: [www.hpra.ie](http://www.hpra.ie); E-mail: [medsafety@hpra.ie](mailto:medsafety@hpra.ie). By reporting side effects you can help provide more information on the safety of this medicine.**

## **5. How to store Transiderm-Nitro**

Keep out of the reach and sight of children both before and after use.

Do not use the patches after the expiry date which is printed on the pouch and carton. The expiry date refers to the last day of that month.

Keep your patches below 25°C. Store in the original package.

Do not open the sealed sachet until you are going to use the patch.

If your doctor tells you to stop using Transiderm-Nitro patches, please take any which are left back to your pharmacist to be destroyed. Only keep them if the doctor tells you to. Medicines should not be disposed of via waste water or household waste.

These measures will help to protect the environment.

## **6. Further Information**

### **What Transiderm-Nitro contains**

- The active substance of Transiderm-Nitro is glyceryl trinitrate.
- The other ingredients are lactose monohydrate, dimeticone, colloidal anhydrous silica, ethylene-vinyl acetate copolymer, medical adhesive CH15, polyethylene terephthalate and aluminium and printing inks DuroLux 544310 (for Transiderm-Nitro 15) and SICURA Typo UV (for Transiderm-Nitro 5 and 10). See diagram of patch below.

### **What Transiderm-Nitro looks like and the contents of the pack**

The Transiderm-Nitro 5 patch is a flat, foil like patch sealed at the edges with white paste like filling, one side with a greyish orange backing film with imprint 'CG DOD', the other side with an off-white

protective liner. Each Transiderm-Nitro 5 patch contains 25mg of glycerl trinitrate; your body will absorb approximately 5mg over 24 hours. The releasing surface area is 10 cm<sup>2</sup>.

The Transiderm-Nitro 10 patch is a flat, foil like patch sealed at the edges with white paste like filling, one side with a greyish orange backing film with imprint 'CG DPD', the other side with an off -white protective liner. Each Transiderm-Nitro 10 patch contains 50mg of glycerl trinitrate; your body will absorb approximately 10mg over 24 hours. The releasing surface area is 20 cm<sup>2</sup>.

The Transiderm-Nitro 15 patch is a flat, foil like patch sealed at the edges with white paste like filling, one side with a greyish orange backing fi lm with imprint 'CG EJE', the other side with an off -white protective liner. Each Transiderm-Nitro 15 patch contains 75mg of glycerl trinitrate; your body will absorb approximately 15mg over 24 hours. The releasing surface area is 30cm<sup>2</sup>.

Transiderm-Nitro 5 and 10 come in packs containing 28 patches. Transiderm-Nitro 15 come in packs containing 30 patches. Each patch comes in a sealed sachet inside the pack. The patch should not be used if the seal is broken.

### **Marketing Authorisation Holder**

Sandoz Pharmaceuticals d.d.  
Verovškova ulica 57  
1000 Ljubljana  
Slovenia

### **Manufacturer**

Novartis Pharma GmbH,  
Roonstraße 25,  
D-90429 Nuremberg,  
Germany  
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## **7. How to apply the patch**

1. Decide where you will put the patch. It is important that you put it on a hairless area to ensure that it sticks well. The side of the chest or upper arm is recommended. The skin should not be inflamed, broken or irritated.



2. Wash the skin and dry it thoroughly to make sure the patch sticks well. Wait a minute until the skin feels quite dry. Do not use creams, lotions, oil or powder.



3. Remove one sachet from the box and tear open the sachet at the notch. Use your fingers, as cutting with scissors might damage the patch inside. Remove the patch from the sachet.



4. Peel off the white plastic backing and discard it. Do not touch the sticky surface of the patch.



5. Place the sticky side of the patch on the clean skin, press firmly while you count slowly up to five.



6. Run your finger around the edge of the patch to make sure no air or water can get in. If you have applied the patch correctly you can bathe, shower or swim with little risk of the patch coming off .



7. 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 sticky feeling left on the skin can be removed with alcohol.