**IE/H/109/001-003/II/023**

# PACKAGE LEAFLET: INFORMATION OF THE USER

**Dermatrans 5 mg/24 h transdermal patch**
**Dermatrans 10 mg/24 h transdermal patch**
**Dermatrans 15 mg/24 h transdermal patch**

**Glyceryl trinitrate**

**Read all of this leaflet carefully before you start using this medicine because it contains important information for you.**
- 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 only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

**What is in this leaflet:**


## 1. What Dermatrans is and what it is used for

Dermatrans patches contain the active substance glyceryl trinitrate, a vasodilator used in cardiac diseases, which belongs to a group of drugs called organic nitrates.
Dermatrans patches are applied to the skin and the active substance will then pass continuously through your skin and into your body.
Dermatrans is indicated for the prevention of angina attacks either taken on its own or in combination with other anti-anginal therapy.
Angina usually occurs as a pain or tightness in the chest although it may be felt in the neck or arm. Pain occurs when the heart is not sufficiently oxygenated. Dermatrans is not indicated for the treatment of acute attacks. You should use your usual sublingual tablet or spray for treatment of acute attacks.

Dermatrans patches are for external use only.

## 2. What you need to know before you use Dermatrans

**Do not use Dermatrans*:***

- if you are allergic (hypersensitive) to glyceryl trinitrate, related organic nitrates or to any of the other excipients of Dermatrans (listed in section 6);

- if you have or you have recently had a shock associated with very low pressure;
- if you have medical conditions such as headaches, vomiting or seizures associated with increased intracranial pressure, including that caused by head trauma;
- if you suffer from heart failure due to obstruction as, for example, in presence of a narrowing of the aortic orifice or atrioventricular orifice of the heart (aortic stenosis or mitral stenosis, respectively), or of a fibrotic thickening of the thin, sac-like membrane that surrounds the heart (constrictive pericarditis).
- if you are taking medicinal products for the treatment of erectile dysfunction (e.g. sildenalfil or any other PDE-5 inhibitors). Nitrates must not be administered in patients treated with sildenafil or any other medicines used to treat erectile dysfunction. Patients currently under nitrates must not take sildenafil or any other medicines for the treatment of erectile dysfunction. The combination of a nitrate with sildenafil or any other PDE-5 inhibitors may cause a deep and sudden fall of blood pressure, which may lead to fainting, loss of consciousness or even a heart attack (see also "**Taking other medicines**");
- if you are taking medicinal products with riociguat, a soluble guanylate cyclase stimulator;
- if you have severe low blood pressure (maximum blood pressure less than 90 mm Hg);
- if you have a severe decrease in the volume of blood in your body due to blood loss or loss of body fluids (severe hypovolemia).
- if you have severe anaemia;
- if you have a toxic fluid retention in the lungs (toxic pulmonary oedema).

**Warnings and precautions**

Talk to your doctor or pharmacist before using Dermatrans:

- if you withdraw the treatment. The withdrawal of Dermatrans treatment must be gradual, by replacement with decreasing doses of long-acting oral nitrates;
- if you should attempt magnetic resonance imaging, electrical stimulation of your heart for the reestablishement of the normal cardiac rhythm (defibrillation or cardioversion), and before heat therapy (diathermy). You must remove Dermatrans patches before undergoing these treatments;
- if you have or have recently had a heart attack (myocardial infarction) or if you quickly develop symptoms of heart failure (acute heart failure) such as breathlessness, feeling very tired, swelling of legs. Your doctor may ask you to perform laboratory examinations on your cardiovascular functions;
- if you have severe low blood pressure while you are under treatment with Dermatrans, it may be necessary to remove the patch. In case you experience collapse or shock, Dermatrans patch should be removed;
- if you experience chest pain (acute anginal attacks), or if your heart does not get enough blood flow and oxygen (unstable angina) or in the case of heart attack (myocardial infarction). Dermatrans must not be used as an immediate treatment for these conditions;
- if you experience severe headache or abnormal low blood pressure (hypotension). This may happen if the initial dose is too high. It is advisable to increase the dose gradually until the optimal effect is achieved;

- if you are taking other nitrates or sublingual glyceryl trinitrate because your organism may build up a resistance to the effects of these substances after repeated exposure (cross-tolerance);
- if you have or have had glyceryl trinitrate-induced abnormal low blood pressure. In this case, you may experience low heart rate (paradoxical bradycardia) and increased angina;
- if you suffer from a disease of the optic nerve (closed angle glaucoma);
- if you have insufficient oxygenation of blood (hypoxaemia) due to severe anaemia, or lung disease, or reduced blood supply to your heart (ischaemic heart failure).
  Patients with these medical conditions frequently suffer from an imbalance of ventilation/perfusion ratio which is an index of respiratory function. In these patients glyceryl trinitrate could worsen the ventilation/perfusion imbalance and cause a further decrease of blood oxigenation;
- if angina is caused by the thickening of your heart (hypertrophic cardiomyopathy). Nitrates may worsen this type of angina;
- if you experience an increased frequency of anginal attacks during the patch-off periods. Your doctor may evaluate the suitability of an additional antianginal therapy.
- if you experience a sensitisation phenomena of the skin (itching, burning, inflammation), treatment should be discontinued and a doctor should be consulted.

**Other medicines and Dermatrans**

The concurrent administration of medicinal products for treatment of erectile dysfunction (e.g. sildenafil or any other PDE-5 inhibitors) potentiates the blood pressure lowering effects of nitrates and therefore must be avoided (see also "**Do not use Dermatrans**").

Concomitant treatment with riociguat , a soluble guanylate cyclase stimulator must be avoided since concomitant use can cause hypotension (see also "**Do not use Epinitril**").

Concomitant treatment with
- medicines used to lower high blood pressure, as e.g. calcium antagonists, ACE inhibitors (for the treatment of congestive heart failure), beta-blockers (used to manage cardiac arrhytmias), diuretics (increase the excretion of water from the body), and other antihypertensives,
- tricyclic antidepressants (medicines for the treatment of depressive disorders),
- neuroleptics (medicines used to manage psychosis) and
- major tranquillisers (sedatives),
- as well as with alcohol and with the association of amifostine (cytoprotective medicine in chemo- and radiotherapy) and
- acetyl salicylic acid (an NSAID),

may potentiate the blood pressure lowering effects of Dermatrans.

Concomitant treatment with dihydroergotamine may reduce the effect of Dermatrans.

Non-steroidal anti-inflammatory drugs, except for acetyl salicylic acid, may decrease the therapeutic response to Dermatrans.

Tell your doctor or pharmacist if you are taking, have recently taken, or might take any other medicines.

**Pregnancy, breast-feeding and fertility**

Dermatrans should not be used during pregnancy, especially in the first three months, unless your doctor has told you.

Due to the limited information on the presence of glyceryl trinitrate in human breast-milk, a risk to the suckling child cannot be excluded. Your doctor will evaluate whether to discontinue breast-feeding or Dermatrans.

No data are available on the effect of Dermatrans on fertility in humans.

If you are pregnant or breast-feeding, think you may be pregnant or planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

**Driving and using machines**
Especially at the start of treatment or in case of dose adjustments, Dermatrans may influence your ability to drive or use machines, since it may impair your reactions or might rarely cause low blood pressure in the standing position and dizziness, as well as, in exceptional cases, fainting after overdosing.

If you experience these effects, you should not drive or use machines.

## 3. How to use Dermatrans

Always use Dermatrans exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

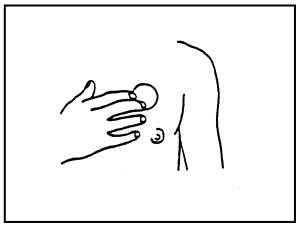
The recommended dose is one patch Dermatrans once daily. Apply the patch to your skin thoroughly and retain it for 12-16 hours. Then, remove the patch and take a patch-free interval for the remaining 8-12 hours.
You must change your Dermatrans patch according to the instructions given by your doctor. Your doctor will tell you how long to keep the patch on your skin and the length of the patch-free interval.

**Use in children and adolescents**
Dermatrans should not be used in children and adolescents below the age of 18.

**How long should you use Dermatrans**
Treatment with Dermatrans may be continued for several years, however your doctor will want to see you regularly to decide whether to continue with treatment or to change the therapeutic schedule.

**How do you put your patch on**
You should apply the patch to clean, dry skin, but not on top of cuts, spots or blemishes or to an area where you have just applied cream, moisturiser or talc. It is recommended to apply Dermatrans transdermal patches to the skin of the chest (see Figure 1), or outer upper arm, free of redness or irritation and to rotate the sites of application. Suitable area may be shaved if necessary. Areas that form folds or are subjected to friction during movement should be avoided.

Figure 1



Do not apply patches one after the other to the same place.
An Dermatrans patch should be applied to the skin as soon as it is removed from its sachet, as follows:

(I) Tear open the sachet at the indentation.
Do not use scissors (see Figure 2).

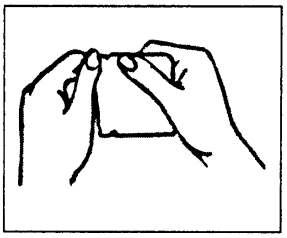


Figure 2

(II) Hold the patch between your thumb and index finger at the pull-off tag (see Figure 3).

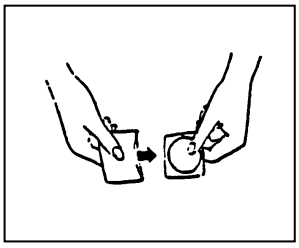


Figure 3

(III) Peel off the protective liner with the other hand (see Figure 4). Do not touch the sticky side of the patch otherwise it will not stick properly.

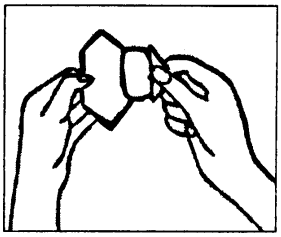


Figure 4

(IV) Apply the open part of the patch to your skin

and remove the remaining part of the protective liner. Press firmly for about 10 seconds on the whole surface of the patch. Run your finger along the edges to make sure it is firmly stuck down.

Wash your hands before and after applying Dermatrans.

To remove a patch, just peel away at the edge and pull the patch smoothly until it comes off. After use, fold the patch in half, sticky side inwards and throw in a dustbin where children cannot reach it.

**What to do if the patch falls off**
If Dermatrans is applied correctly, it is most unlikely that the patch will fall off. However if the patch does fall off, replace it with a new one and then change the patch again as usual following your original regular schedule.

**If you use more Dermatrans than you should**
If you take high doses of glyceryl trinitrate, you may experience severe low blood pressure, increased heart rate or collapse and fainting, as well as haemoglobin alteration (methaemoglobinaemia).

If you or someone else applies too many patches at once, remove the patches carefully and wash the underlying skin thoroughly to reduce absorption. In case that you experience low blood pressure or collapse, elevation or, if necessary, compression bandaging of the legs is recommended.

**If you forget to change the patch**
If you forget to change the patch at the right time, you should replace it as soon as possible, and then follow your original regular schedule for applying the next patch.

**If you stop using Dermatrans**
When stopping the treatment with Dermatrans, you may experience a recurrence of anginal attacks.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

## 4. Possible side effects

Like all medicines, Dermatrans can cause side effects, although not everybody gets them.
The following side-effects have been reported:

**Very common side effects (occur in more than 1 patient out of 10):**
- Nausea.
- Vomiting.

**Common side effects (occur in more than 1 and less than 10 patients out of 100):**
- Headache.

**Uncommon side effects (occur in more than 1 and less than 10 patients out of 1,000):**
- Contact skin inflammation (dermatitis contact).
- Redness and irritation of the skin at the site of application of the patch.
- Itching.

- Sensation of burning.

**Rare side effects (occur in more than 1 and less than 10 patients out of 10,000):**
- Increased heart rate (tachycardia).
- Low blood pressure in standing position (orthostatic hypotension) which may be described as transient episodes of light headedness.
- Flushing.
- Heart rate increase at diagnostical investigations.

**Very rare side effects (occur in less than 1 patient out of 10,000):**
- Dizziness.
- Fainting (syncope).

**Side effects with unknown frequency:**
- Abnormal heartbeat (palpitation).
- Generalized skin eruption (rash generalized).

If any of these symptoms are troublesome or persist, please consult your doctor.

**Reporting of side effects**
If you get any side effects, talk to your doctor or pharmacist. 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; E-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

## 5. How to store Dermatrans

Keep this medicine out of the sight and reach of children.

Do not store above 25°C. Dermatrans should be stored in its sachet intact.

Do not use this medicine after the expiry date which is stated on the carton and on the sachets. The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

## 6. Contents of the pack and other information

**What Dermatrans contains**

Dermatrans patches contain the active substance glyceryl trinitrate and are available in three strengths:

| | |
|---|---|
| Dermatrans 5 mg/24 h: | contains 15.70 mg of the active substance glyceryl trinitrate and delivers about 5 mg of glyceryl trinitrate per day (0.2 mg/h); the release area of the patch is 6.38 $cm^2$. The identification code printed on the backing foil is NR5. |

| | |
|---|---|
| Dermatrans 10 mg/24 h: | contains 31.37 mg of the active substance glyceryl trinitrate and delivers about 10 mg of glyceryl trinitrate per day (0.4 mg/h); the release area of the patch is 12.75 $cm^2$. The identification code printed on the backing foil is NR10. |
| Dermatrans 15 mg/24 h: | contains 47.04 mg of the active substancet glyceryl trinitrate and delivers about 15 mg of glyceryl trinitrate per day (0.6 mg/h); the release area of the patch is 19.12 $cm^2$. The identification code printed on the backing foil is NR15. |

The other ingredients are an adhesive substance (acrylate-vinylacetate copolymer), a tackifier (hydroabietyl phthalate) and a cross-linker (butyltitanate polymer), which have been spread together with the active ingredient on a backing foil (lacquered polypropylene foil). The adhesive layer is covered by a two sided aluminised and siliconised protective liner which is removed prior to use.

**What Dermatrans looks like and contents of the pack**

Dermatrans are transdermal adhesive backed patches. Each patch is individually sealed in a protective sachet.

Pack sizes: 15 and 30 patches. Not all pack sizes may be marketed.

**Marketing Authorisation Holder**

ROTTAPHARM Ltd.
Damastown, Industrial Park, Mulhuddart
Dublin 15
Ireland.

**Manufacturer**

ROTTAPHARM Ltd.
Damastown, Industrial Park, Mulhuddart
Dublin 15
Ireland.

and/or

LTS Lohmann Therapie Systeme AG
Lohmannstraβe 2
56626 Andernach
Germany

**This medicinal product is authorised in the Member States of EEA under the following names:**

| *Country* | *Name* |
|---|---|
| Ireland | Dermatrans |
| Italy | Dermatrans |
| Spain | Dermatrans |

**This leaflet was last revised in March 2022**