

**B. PACKAGE LEAFLET**

## **Package leaflet: Information for the patient**

### **Minitran 5 mg, 10 mg or 15 mg transdermal patches** 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. 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.
- In this leaflet, Minitran 5 mg, 10 mg or 15 mg transdermal patches will be called Minitran patches.

#### **What is in this leaflet**

1. What Minitran patches are and what they are used for
2. What you need to know before you use Minitran patches
3. How to use Minitran patches
4. Possible side effects
5. How to store Minitran patches
6. Contents of the pack and other information

#### **1. What Minitran patches are and what they are used for**

Minitran patches contain the active substance glyceryl trinitrate and belong to a group of medicines called vasodilators which work by widening blood vessels. This helps blood which is carrying oxygen reach the muscle in your heart.

When you apply a Minitran patch to your skin the medicine passes through your skin and into your bloodstream.

Minitran patches are used to help prevent angina attacks (chest pains). Minitran patches may be used on their own, or with other treatments for angina prescribed by your doctor.

The Minitran 5 mg patch is also used by doctors and nurses to keep veins open and improve blood flow when you are given a drip (intravenous infusion).

If you have angina it is important that you receive effective treatment. If angina is left untreated the muscle in your heart can become starved of oxygen and this could cause a potentially fatal heart attack (myocardial infarction).

#### **2. What you need to know before you use Minitran patches**

##### **Do not use Minitran patches if:**

- You are taking Viagra (sildenafil) for male erection problems. A severe and potentially fatal drop in blood pressure can occur if these two medicines are used together
- You are allergic to glyceryl trinitrate or any of the other ingredients in Minitran patches (see Section 6)

- You have severe anaemia
  - You have glaucoma (high pressure in your eye) or you have been told that you have high pressure inside the skull
  - You have heart valve disease or pericarditis (inflammation of the lining of the heart)
  - You have an angina attack. Your doctor will give you a different medicine such as a GTN spray for this
  - Severe hypotension (systolic blood pressure less than 90 mmHg)
  - Severe hypovolemia
  - You are taking Riociguat a medicine used to treat some types of hypertension.
- If any of the above apply to you, talk to your doctor or pharmacist.

### **Children and adolescents**

Minitran patches are not recommended for use in children.

### **Check with your doctor before using Minitran patches if:**

- You suffer from any heart or lung problems. Minitran patches may have to be used under your doctor's supervision
- You are pregnant, or are trying to become pregnant.

### **Other medicines and Minitran patches**

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

- Medicines for failure to achieve an erection such as Viagra. Using Minitran with these medicines could cause a severe drop in your blood pressure.  
**This could make you unconscious and may be fatal**
- Other vasodilators such as nitrates, hydralazine or minoxidil (used to treat high blood pressure and angina)
- Medicines used to lower blood pressure such as beta-blockers, ACE inhibitors and diuretics (water tablets)
- Medicines to treat depression such as amitriptyline and dothiepin
- Medicines to treat psychiatric illnesses such as neuroleptics
- Medicines to treat pain, fever and inflammation such as aspirin or any other non-steroidal anti-inflammatory drug
- Dihydroergotamine, a medicine used to treat migraines
- Any other medicine, including medicines obtained without a prescription.
- Riociguat a medicine used to treat some types of hypertension.

These medicines can interfere with how well your treatment works.

### **Using Minitran patches with food and drink**

Do not drink alcohol whilst using Minitran patches as this can cause your blood pressure to drop. This may make you feel dizzy or faint.

### **Pregnancy, breast-feeding and fertility**

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

### **Driving and using machines**

Minitran patches may make you feel dizzy and faint when you stand up. If this happens to you, do not drive or use machinery.

### 3. How to use Minitran patches

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

The usual starting dose is one Minitran 5 mg patch per day. Your doctor or pharmacist will have chosen the strength which best suits your condition. You should check with your doctor or pharmacist if you are unsure.

Remember: Each Minitran patch is contained in a sealed pouch. The sticky side of the patch is covered by a disposable liner which must be removed and thrown away before the patch is applied to your skin.

#### How many patches to use

Normally one patch per day is sufficient.

#### When to apply the patches

- At the start of your treatment, put on a patch in the morning
- Remove the patch before you go to bed.
- You should have 8 to 12 hours without a patch on. This will prevent you from becoming tolerant to the medicine and will ensure the treatment remains effective
- Each morning put on a new patch
- You can keep the patch in place whilst bathing, showering or swimming.

#### How and where to apply the patch

- Choose a smooth area of skin to apply the patch. The area should be hairless to ensure good contact of the patch with the skin. The chest, upper arm or shoulders are suitable
- Your hands and the skin where you will apply the patch should be clean and dry.

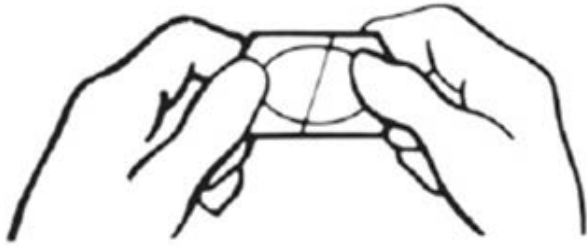
Do not use powder or moisturiser.

#### Instructions for applying a Minitran patch

- Starting at the notched corner of the pouch, tear along the dotted line. Open the pouch and remove the patch.



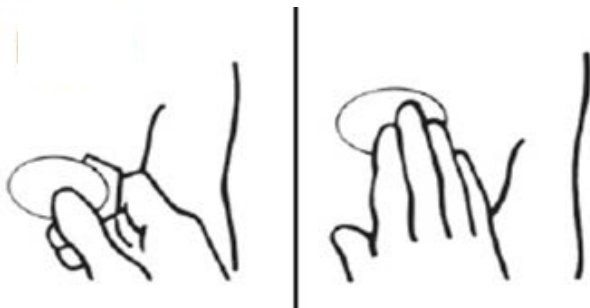
- Fold the patch along the dotted line, so that the backing comes apart.



- Hold the patch on one side and peel off the backing on the other side to expose the sticky patch. Discard the liner. Place the sticky side of the patch directly onto the skin.



- Peel off the remainder of the backing and discard the liner. Press down firmly on the patch with the palm of your hand.



Occasionally a patch may not stick or it may fall off. If this happens apply a new patch to a different area of the skin.

**When applying the patch you must not:**

- Stretch the skin
- Place the patch on a cut or reddened area of skin
- Stick the same patch back on once it has been removed from the skin.

**When applying the patch you should always:**

- Place the new patch on a different area of skin
- Allow several days to pass before applying a fresh patch to the same area of skin.

**For patients receiving an intravenous infusion (drip)**

Minitran patches can be used when you are being given a drip. Your doctor or nurse will decide on the strength of the patch required and apply the patch next to the needle that goes into the vein. The patch will be changed daily. It will be removed once your drip is stopped.

**If you use more Minitran patches than you should**

Do not use more Minitran patches than you should. If you accidentally apply too many patches, remove the patches straight away and immediately contact the nearest hospital casualty department or your doctor.

An overdose of Minitran patches can cause a rapid drop in blood pressure causing dizziness or fainting.

**If you forget to use Minitran patches**

If you forget to use a new patch apply it as soon as you remember. If you are not sure when to use your patch please ask your doctor or pharmacist.

**If you stop using Minitran patches**

Do not stop using Minitran patches without first talking to your doctor or pharmacist.

**4. Possible side effects**

Like all medicines, this medicine can cause side effects, although not everybody gets them.

**Possible side effects include:**

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

- Feeling and being sick.

*Common (affects 1 in 100 people):*

- Headache. This usually disappears after a few days. If you have a lasting headache you should talk to your doctor

*Uncommon (affects 1 in 1,000 people):*

- Slight reddening, itching or burning sensation on the skin where you have applied the patch. This usually disappears after the patch has been removed

*Rare (affects 1 in 10,000 people):*

- An abnormally fast heart beat
- Hot flushes

*Very rare (affects less than 1 in 10,000 people)*

- Dizziness

*Not known (frequency cannot be estimated from the available data)*

- Skin rash
- Palpitations (noticeable pounding, fluttering or irregular heartbeat)
- Fainting

**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 the

Yellow Card Scheme at: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard). By reporting side effects you can help provide more information on the safety of this medicine.

## **5. How to store Minitran patches**

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

Do not use Minitran patches after the expiry date on the sachet. The expiry date refers to the last day of that month. Store Minitran patches at room temperature (below 25 °C) in a dry place. Do not expose to light. The shelf life for Minitran patches is three years.

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 Minitran patches contain**

The active substance in Minitran patches is glyceryl trinitrate.

- The Minitran 5 mg patch contains 18 mg of glyceryl trinitrate. The average amount delivered into the bloodstream in 24 hours is 5 mg
- The Minitran 10 mg patch contains 36 mg of glyceryl trinitrate. The average amount delivered into the bloodstream in 24 hours is 10 mg
- The Minitran 15 mg patch contains 54 mg of glyceryl trinitrate. The average amount delivered into the bloodstream in 24 hours is 15 mg.

The other ingredients are: isooctyl acrylate/acrylamide copolymer, ethyl oleate, glyceryl monolaurate.

### **What Minitran patches look like**

Minitran patches are oval shaped and come in a square pouch or sachet with a tear-off top. Each patch is protected by a clear, disposable, plastic film liner that must be removed before use. The liner is split and comes off as two pieces of film.

Minitran patches come in packs of 30.

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