

# Minitran™

(mini-tran)

Transdermal Delivery System

Glyceryl trinitrate (*gliss-er-ill tri-nite-rate*)

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## Consumer Medicine Information

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### What is in this leaflet

This leaflet answers some common questions about Minitran.

**It does not contain all 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 risk of you using Minitran against the benefits they expect it will have for you.

**If you have any concerns about using Minitran please ask your doctor or pharmacist.**

**Keep this leaflet with the medicine.**

You may want to read it again.

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### What Minitran is used for

Minitran is used to help prevent angina attacks (chest pain). It is an adhesive patch that delivers a medicine called glyceryl trinitrate through the skin and into the bloodstream.

Glyceryl trinitrate belongs to a group of medicines called nitrates. When a Minitran patch is placed on the skin, glyceryl trinitrate passes slowly through the skin and into the blood stream. Glyceryl trinitrate works by widening blood vessels, letting more blood and oxygen reach the heart.

**Ask your doctor if you have any questions about why this medicine has been prescribed for you.**

Your doctor may have prescribed it for another reason.

There is not enough information to recommend this medicine for children.

Minitran is available only with a doctor's prescription.

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### Before using Minitran

#### ***When you must not use it***

**Do not use Minitran if you are allergic to:**

- glyceryl trinitrate (the active ingredient) or any other ingredients of Minitran listed at the end of this leaflet.
- any other medicine or food containing nitrates or nitrites

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives of the skin.

**Do not use Minitran if you have any of the following medical conditions:**

- severe anaemia
- raised pressure in the eye from any cause
- increased pressure in the head from any cause (such as stroke, tumour, head injury)
- disease in your heart valves or inflammation of your heart.

If you are not sure whether any of these conditions apply to you, your doctor can advise you.

**Do not use Minitran if you are taking medicines called phosphodiesterase inhibitors, such as sildenafil, vardenafil or tadalafil used treat impotence in men and/or for treating high blood pressure in the lungs in men and women.**

If you use these medicines together with Minitran, your blood pressure may fall to a dangerously low level.

**Do not use Minitran if you are using a medicine called riociguat used to treat high blood pressure in your lungs.**

**Do not use this medicine after the expiry date printed on the pouch or if the package is torn or shows signs of tampering.**

If it has expired or is damaged, return it to your pharmacist for disposal.

#### ***Before you start to use it***

**Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.**

**Tell your doctor if you have any of the following medical conditions:**

- low blood pressure
- heart problems or blood vessel disorder other than angina
- low oxygen levels in your blood.

Your doctor may want to take special precautions if you have any of the above conditions.

**Tell your doctor if you are pregnant or breast-feeding.**

The safety of Minitran in pregnancy has not been established. It is unknown whether Minitran passes into breast milk.

Your doctor can discuss with you the risks and benefits involved.

**If you have not told your doctor about any of the above, tell them before you start using Minitran.**

**Do not use Minitran on anyone else even if you think their condition is the same as yours.**

Minitran has been prescribed for you only.

### ***Taking other medicines***

**Tell your doctor or pharmacist if you are taking any other medicines including any that you get from your pharmacy, supermarket or health food shop.**

Some medicines and Minitran may interfere with each other. These include:

- other medicines for angina
- medicines for high blood pressure or heart problems
- diuretic medicines, also called water or fluid tablets
- medicines used to treat depression called tricyclic antidepressants
- medicines for mental disorders
- dihydroergotamine, a medicine for migraine
- any medicines that you buy without a prescription
- sildenafil, tadalafil or vardenafil used to treat impotence in men or high blood pressure in the lungs in men and women
- riociguat used to treat high blood pressure in your lungs.

These medicines may be affected by Minitran or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Your doctor and pharmacist have more information on medicines to be

careful with or avoid while using this medicine.

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## **How to use Minitran**

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**Follow all directions given to you by your doctor or pharmacist carefully.**

They may differ from the information contained in this leaflet.

**If you do not understand the instructions on the product label, ask your doctor or pharmacist for help.**

### ***How much to use***

Your doctor may start your treatment with one Minitran 5 patch every day and then change to a larger Minitran 10 or Minitran 15 patch if required. Your doctor will prescribe the correct dose for you.

### ***When to use it***

**Apply a new patch at the same time every day, usually in the morning.**

Your doctor will likely ask you to take the patch off for 8 to 12 hours of every 24 hours (e.g. take the patch off at bedtime and put a new one on when you wake up in the morning).

This patch-free period helps maintain the effectiveness of the medicine.

### ***How to apply the patch***

**Follow these steps to apply a patch to your skin:**

#### **1. Choose an area of skin:**

- The best place is your chest but you may use any area except below your knees or elbows.
- Choose an area of skin that has no sores, cuts or rashes.
- If the skin is very hairy, you can clip the hair (do not shave it) so the patch sticks well and won't be hard to remove.
- Use a different area of skin each day. Wait several days before using the same area again.

#### **2. Make sure the skin is clean, cool, dry and free from creams, lotions or oils:**

- You may need to wash the area with soap and water and dry it thoroughly.
- After a shower or bath, wait a few minutes before applying the patch to make sure your skin is completely cool and dry.

#### **3. Open the sachet that contains the patch:**

- Start at the notched corner.
- Tear pouch along the dotted line.
- Do not use scissors because you may accidentally cut the patch and the medicine may leak out.

#### **4. Remove the protective liner from the sticky side of the patch:**

- Bend the patch so that the tab on the liner pops up.
- Hold the tab to peel off the liner.
- Apply sticky side of the patch to the upper arm or chest.
- Remove and discard the other piece of liner.
- Press patch firmly into place.

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

**If a patch does not stick or falls off, use a new patch on a different area of skin.**

- Apply a new patch to a different area of clean, dry skin.
- Change the patch at the same time that you would normally change it.

**Do not re-use a patch once it has been removed from the skin.**

You can bathe, shower and swim as normal when wearing a Minitran patch.

### ***How long to use it***

**Continue using Minitran for as long as your doctor tells you.**

This medicine helps control your condition, but does not cure it. It is important to keep using your medicine even if you feel well.

## ***If you forget to use Minitran***

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

Otherwise, apply the patch as soon as you remember, respecting any prescribed patch-off period and then go back to using Minitran as you would normally.

**Do not use 2 patches to make up for the one that you missed.**

This may increase the chance of you getting an unwanted side effect.

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

## ***If you use too much (overdose)***

Glyceryl trinitrate overdose is unlikely when using Minitran patches.

**If accidental overdose does occur, remove the patch and contact your doctor or Poisons Information Centre (telephone 13 11 26), or go to Accident and Emergency at your nearest hospital.**

Some of the symptoms of an overdose may include light-headedness or fainting. This is because your blood pressure is too low.

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## **While you are using Minitran**

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### ***Things you must do***

**Tell your doctor if you continue to have angina attacks or if they become more frequent while you are using Minitran. Keep a record of the number of attacks, when they happen and the possible cause (for example, during exercise or during the period when the patch is off).**

This helps your doctor give you the best possible treatment.

**If you become pregnant while taking Minitran, tell your doctor immediately.**

Your doctor can discuss with you the risks of using Minitran while you are pregnant.

**If you are about to be started on any new medicine, remind your doctor and pharmacist that you are using Minitran.**

**Tell any other doctor, dentist or pharmacist who treats you that you are using Minitran.**

### ***Things you must not do***

**Do not use Minitran to relieve an attack of angina.**

Minitran will not relieve an attack of angina once it has started. Your doctor will have given you other tablets or spray to use if you get attacks of angina.

**Do not stop using Minitran suddenly.**

Stopping Minitran suddenly may bring on attacks of angina, especially if you have been using it for several weeks or more.

If your doctor asks you to stop using Minitran, your doctor will gradually reduce the dose over 4 to 6 weeks before you completely stop using it.

**Do not give this medicine to anyone else, even if their condition seems similar to yours.**

### ***Things to be careful of***

**Be careful if you are driving or operating machinery until you know how Minitran affects you.**

Minitran patches may lower your blood pressure and make you feel dizzy or lightheaded, particularly when changing position suddenly.

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

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. If this problem continues or gets worse, talk to your doctor.

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## **Side Effects**

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**Tell your doctor or pharmacist as soon as possible if you do not feel well while you are using Minitran.**

This medicine helps most people with angina, but it may have unwanted side 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 attention if you get some of the side effects.

**Do not be alarmed by the following lists of side effects. You may not experience any of them.**

**Ask your doctor or pharmacist to answer any questions you may have.**

**Tell your doctor or pharmacist as soon as possible if you notice any of the following and they worry you:**

- headaches

These may develop when you begin using Minitran. They are usually mild and stop after the first few days of treatment.

- reddening of the skin after the patch has been taken off, with or without itching

If this happens it usually only lasts a few hours. Ensuring your skin is dry before you apply a patch and using a different area of skin each day can help prevent redness and irritation.

Other common side effects include:

- dizziness
- light headedness
- low blood pressure
- hot flushes
- nausea and vomiting.

**Tell your doctor immediately or go to Accident and Emergency at your nearest hospital if you notice any of the following:**

- signs of an allergic reaction such as rash, itching or hives on the skin; swelling of the face, lips, tongue or other part of the body; shortness of breath, wheezing or troubled breathing

- severe redness, swelling or blisters under the patch
- chest pains that are not relieved by taking your usual medicine for treating an angina attack
- severe headache.

**Tell your doctor or pharmacist if you notice anything that is making you feel unwell.**

Other side effects not listed above may also occur in some people.

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## After using Minitran

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### **Storage**

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

If you take the patches out of the pouch they may not keep well.

**Keep Minitran patches in a cool, dry place where the temperature stays below 25°C.**

**Do not keep Minitran patches in the fridge.**

**Keep Minitran patches where children cannot reach them.**

### **Disposal**

**Dispose of used Minitran patches where children cannot reach them.**

Used patches still contain some of the active ingredient which could harm a child.

**If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.**

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## Product Description

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

Minitran is a patch made of thin, clear plastic covered by a layer of adhesive and the active ingredient, glyceryl trinitrate.

Minitran patches are oval shaped and are available in three sizes:

MINITRAN 5 is a 6.7 cm squared patch. It releases 5 mg of glyceryl trinitrate over 24 hours. The patch is marked "MINITRAN 5".

MINITRAN 10 is a 13.3 cm squared patch. It releases 10 mg of glyceryl trinitrate over 24 hours. The patch is marked "MINITRAN 10".

MINITRAN 15 is a 20 cm squared patch. It releases 15 mg of glyceryl trinitrate over 24 hours. The patch is marked "MINITRAN 15".

Each box of Minitran contains 30 patches.

### **Ingredients**

- Minitran 5 contains 18 mg of glyceryl trinitrate
- Minitran 10 contains 36 mg of glyceryl trinitrate
- Minitran 15 contains 54 mg of glyceryl trinitrate.

Each Minitran patch also contains:

- polymer 3273
- ethyl oleate
- glyceryl laurate.

Australian Registration Numbers:

Minitran 5 AUST R 52028

Minitran 10 AUST R 52029

Minitran 15 AUST R 52030

### **Sponsor**

Minitran is supplied by:

**iNova Pharmaceuticals (Australia) Pty Limited**

ABN 13 617 871 539

Level 10, 12 Help Street

Chatswood NSW 2067

Tel: 1800 630 056

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