Consumer Medicine Information (CMI) summary

The <u>full CMI</u> on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using Minitran?

Minitran contains the active ingredient glyceryl trinitrate. Minitran is used to help prevent angina attacks (chest pain).

For more information, see Section <u>1. Why am I using</u> <u>Minitran?</u> in the full CMI.

2. What should I know before I use Minitran?

Do not use if you have ever had an allergic reaction to Minitran or any of the ingredients listed at the end of the CMI, or other medicines or foods containing nitrates or nitrites.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section <u>2. What should I know</u> <u>before I use Minitran?</u> in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Minitran and affect how it works.

A list of these medicines is in Section <u>3. What if I am</u> <u>taking other medicines?</u> in the full CMI.

4. How do I use Minitran?

Apply a new patch at the same time every day, usually in the morning. Remove the patch at bedtime. More instructions can be found in Section <u>4. How do I</u> <u>use Minitran?</u> in the full CMI.

5. What should I know while using Minitran?	
Things you should do	 Remind any doctor, dentist or pharmacist you visit that you are using Minitran. Tell your doctor if you continue to have angina attacks or if they become more frequent.

	 If you become pregnant while using Minitran, tell your doctor immediately.
Things you should not do	 Do not stop using this medicine suddenly as this may bring on angina attacks. Do not use Minitran to relieve an attack of angina.
Driving or using machines	 Be careful if you are driving or operating machinery until you know how Minitran affects you. Minitran may lower your blood pressure and make you feel dizzy or lightheaded.
Drinking alcohol	 Drinking alcohol while using Minitran is not recommended. Alcohol may increase the blood pressure lowering effects of Minitran.
Looking after your medicine	 Store below 25°C in a cool dry place. Do not keep Minitran patches in the fridge.

For more information, see Section <u>5. What should I know</u> while using Minitran? in the full CMI.

6. Are there any side effects?

Common side effects include headaches, reddening and itchiness of the skin after removing the patch, dizziness, light headedness, low blood pressure, hot flushes, nausea, and vomiting.

Serious side effects include allergic reaction, 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. Seek immediate medical assistance if these side effects occur.

For more information, including what to do if you have any side effects, see Section <u>6. Are there any side</u> <u>effects?</u> in the full CMI.

Minitran™

Active ingredient(s): Glyceryl trinitrate

Consumer Medicine Information (CMI)

This leaflet provides important information about using Minitran. You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Minitran.

Where to find information in this leaflet:

- 1. Why am I using Minitran?
- 2. What should I know before I use Minitran?
- 3. What if I am taking other medicines?
- 4. How do I use Minitran?
- 5. What should I know while using Minitran?
- 6. Are there any side effects?
- 7. Product details

1. Why am I using Minitran?

Minitran contains the active ingredient glyceryl trinitrate.

Minitran is an adhesive patch which is applied to the skin. It contains the active ingredient glyceryl trinitrate. Minitran is 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. The glyceryl trinitrate in Minitran enters your body in a controlled way, a little at a time. The glyceryl trinitrate causes the blood vessels to relax and increases the supply of blood and oxygen to the heart reducing the likeliness of having an angina attack.

Minitran is used to help prevent angina attacks (chest pain).

2. What should I know before I use Minitran?

Warnings

Do not use Minitran if:

- you are allergic to glyceryl trinitrate, or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can use this medicine.
- you are allergic to other medicines or foods containing nitrates or nitrites.

- you have any of the following medical conditions:
 - severe anaemia (low iron levels in your blood or low red blood cell count)
 - an eye disease called closed angle glaucoma or 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.
 - you are taking medicines for erectile dysfunction, such as sildenafil, vardenafil or tadalafil
 - you are taking medicines for treating high blood pressure in your lungs such as riociguat, sildenafil, or tadalafil. If you use these medicines together with Minitran, your blood pressure may fall to a dangerously low level.
 - you experience lightheadedness, dizziness or fainting when going from lying or sitting to standing up (postural hypotension).

Check with your doctor if you:

- have allergies to any other medicines, foods, preservatives, or dyes.
- have any other medical conditions including
 - 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.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section <u>6. Are there any side effects</u>?

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

The safety of Minitran in pregnancy has not been established.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

It is unknown whether Minitran passes into breast milk.

Use in the Elderly

Severe low blood pressure, particularly when standing upright, may occur with even small doses of Minitran, particularly in the elderly. This may increase the risk of a fall.

Use in Children

Minitran is not recommended for use in children.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins, or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may interfere with Minitran and affect how it works.

Medicines that may <u>increase</u> the effect of Minitran include:

- other medicines for angina
- medicines for high blood pressure or heart problems such as:
 - diuretics, also called water or fluid tablets
 - calcium channel blockers
 - beta blockers
 - ACE inhibitors
- medicines used to treat depression called tricyclic antidepressants
- medicines for mental disorders
- dihydroergotamine, a medicine for migraine.

These medicines may increase the blood pressure lowering effects of Minitran, which may cause dizziness, lightheadness or fainting.

Do not use medicines for erectile dysfunction, such as sildenafil, vardenafil or tadalafil or medicines for treating high blood pressure in your lungs such as riociguat, sildenafil, or tadalafil at the same time as Minitran. If you use these medicines together with Minitran, your blood pressure may fall to a dangerously low level.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Minitran.

4. How do I use Minitran?

How much to use

Your doctor will prescribe the correct dose for you.

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.

When to use Minitran

Follow the instructions provided and use Minitran until your doctor tells you to stop.

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.

Where to apply the Minitran patch

- Apply the Minitran patch to the chest, shoulders, upper arm or back. Do not apply Minitran to the lower arm or lower leg.
- Choose an area of skin that is clean, dry and free of irritation or cuts. The skin should be a non-hairy area so that the hair will not prevent direct contact of the patch with the skin. If hair is likely to interfere with adhesion of the patch, the area may be clipped but not shaved.
- Use a different skin site each time you use a new Minitran patch. Wait several days before you use the same area again.

How to apply the Minitran patch

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.

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.

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.

After removing a patch

Discard the patch in a manner that prevents accidental ingestion or application by curious children or pets. After normal use, there is still enough medicine in the patch to cause serious harm if they are accidentally eaten or applied.

If you forget to use Minitran

Minitran should be used regularly at the same time each day. If you miss applying your patch at the usual time, and 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.

If you forget to remove the patch at the scheduled time, just remove it as soon as possible and continue to follow your original schedule.

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

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

This may increase the chance of you getting unwanted side effects.

If you use too much Minitran

If you think that you have used too much Minitran, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26), or
- contact your doctor, or

 go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using Minitran?

Things you should do

Call your doctor straight away if you become pregnant.

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

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.

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.

If you experience skin reddening or itchiness when removing the patch

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

Remind any doctor, dentist or pharmacist you visit that you are using Minitran.

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

Things you should 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.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how Minitran affects you.

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

Drinking alcohol

Tell your doctor if you drink alcohol.

Alcohol may enhance the blood pressure lowering effects of glyceryl trinitrate. This may lead to dizziness, lightheadedness, or fainting.

Looking after your medicine

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place where the temperature stays below 25°C for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on windowsills.

Do not keep Minitran patches in the fridge.

Keep Minitran patches where children cannot reach it.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
 headache reddening of the skin	Speak to your doctor if
after the patch has been	you have any of these
taken off, with or without	less serious side effects
itching dizziness light headedness low blood pressure hot flushes nausea and vomiting.	and they worry you.

Serious side effects

Serious side effects	What to do
 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. 	Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at <u>www.tga.gov.au/reporting-problems</u>. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What Minitran contains

Active ingredient (main ingredient)	Glyceryl trinitrate
Other ingredients	polymer 3273
(inactive ingredients)	ethyl oleate
	glyceryl laurate

Do not take this medicine if you are allergic to any of these ingredients.

What Minitran looks 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 contains 18 mg glyceryl trinitrate and releases 5 mg of glyceryl trinitrate over 24 hours. The patch is marked "MINITRAN 5".

Registration number: AUST R 52028.

Minitran 10 is a 13.3 cm squared patch. It contains 36 mg glyceryl trinitrate and releases 10 mg of glyceryl trinitrate over 24 hours. The patch is marked "MINITRAN 10".

Registration number: AUST R 52029.

Minitran 15 is a 20 cm squared patch. It contains 54 mg glyceryl trinitrate and releases 15 mg of glyceryl trinitrate over 24 hours. The patch is marked "MINITRAN 15".

Registration number: AUST R 52030.

Each box of Minitran contains 30 patches.

Who distributes Minitran

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