TRYZAN® CAPS; TRYZAN® TABS

Consumer Medicine Information (CMI) summary

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

1. Why am I taking TRYZAN?

TRYZAN contains the active ingredient ramipril.
TRYZAN is used to treat hypertension, heart failure following a heart attack, kidney problems and to prevent cardiovascular problems and complications.

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

2. What should I know before I take TRYZAN?

Do not take if you have ever had an allergic reaction to ramipril or any of the ingredients listed at the end of the CMI.

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 2. What should I know before I take TRYZAN? in the full CMI.

3. What if I am taking other medicines?

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

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

4. How do I take TRYZAN?

 The usual dose of TRYZAN is 1.25 to 10 mg per day depending on the condition treated.

More instructions can be found in Section <u>4. How do I take TRYZAN?</u> in the full CMI.

5. What should I know while taking TRYZAN?

Things you should do

- Stand or get up slowly, especially from bed or chairs.
- Drink enough water during exercise and hot weather, especially if you sweat a lot.
- If you plan to have surgery that needs a

	general anaesthetic, tell your doctor or dentist. If you are about to have any blood tests, tell the doctor that you are taking TRYZAN.
Things you should not do	 Give TRYZAN to anyone else, even if they have the same condition as you. Take TRYZAN to treat any other complaints unless your doctor or pharmacist tells you to. Stop taking or lower/increase the dosage without checking with your doctor.
Driving or using machines	 Be careful before you drive or use any machines or tools until you know how TRYZAN affects you. As with other ACE inhibitor medicines, TRYZAN may cause light-headedness, dizziness, or drowsiness in some people.

Drinking alcohol	 Tell your doctor that you drink alcohol. If you drink alcohol while taking TRYZAN, you may experience dizziness, drowsiness, or lightheadedness.
Looking after your medicine	 Keep your TRYZAN tablets or capsules in the blister pack until it is time to take them. Keep your TRYZAN tablets or capsules in a cool dry place where the temperature stays below 25°C.

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

6. Are there any side effects?

Common side effects: Feeling light-headed, dizziness, dry cough, headache, nausea or vomiting, stomach pain or discomfort, diarrhoea, indigestion, taste disturbance, muscle cramps or spasms, ringing or buzzing in the ears.

Serious side effects: Severe dizziness or confusion, visual disturbances, speech problems, swelling of face/lips/mouth/tongue/throat causing difficulty in breathing, severe blisters, or bleeding.

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.	

TRYZAN® CAPS; TRYZAN® TABS

Active ingredient: ramipril

Consumer Medicine Information (CMI)

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

Where to find information in this leaflet:

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

1. Why am I taking TRYZAN?

TRYZAN contains the active ingredient ramipril.

TRYZAN is an angiotensin converting enzyme (ACE) inhibitor. TRYZAN works by widening the blood vessels, which reduces the pressure in the vessels, making it easier for your heart to pump blood around your body.

This helps increase the supply of oxygen to your heart, so that when you place extra demands on your heart, such as during exercise, your heart may cope better, and you may not get short of breath as easily.

By increasing the supply of oxygen to your heart, your heart does not have to work as hard and it is under less stress, which may reduce the risk of further damage occurring to it following a heart attack.

TRYZAN also improves blood flow through the small blood vessels found in the kidneys, which helps the kidneys to work more efficiently. This in turn can help to slow down the progression of kidney damage that might result from having diabetes or high blood pressure.

TRYZAN is used to treat the following conditions: Hypertension

TRYZAN is used to lower high blood pressure (hypertension). Everyone has blood pressure. This pressure helps get your blood all around your body. Your blood pressure may be different at different times of the day and can be influenced by how busy or worried you are. You have hypertension when your blood pressure stays higher than is needed, even when you are calm and relaxed.

There are usually no symptoms of hypertension. The only way of knowing that you have hypertension is to have your blood pressure checked on a regular basis. If high blood pressure is not treated it can lead to serious health problems, including stroke, heart disease and kidney failure.

Heart failure following a Heart Attack

TRYZAN may be used after a heart attack. A heart attack occurs when one of the major blood vessels supplying blood to your heart becomes blocked. This means that your heart muscle cannot receive the oxygen it needs and becomes damaged. This may lead to further problems, such as heart failure, irregular heart rhythms and blood clots.

Heart failure means that the heart muscle is weak and cannot pump blood strongly enough to supply all the blood needed throughout the body. Heart failure is not the same as a heart attack and does not mean that the heart stops. Heart failure may start off with no symptoms, but as the condition progresses, patients may feel short of breath or may get tired easily after light physical activity, such as walking. Some patients may wake up short of breath at night. Fluid may collect in different parts of the body, often first noticed as swollen ankles and feet.

Kidney problems

TRYZAN may be used to treat some kidney problems. Some conditions such as diabetes and hypertension can lead to kidney problems. These problems develop slowly over several years. Good control of your blood sugar and blood pressure are important in keeping your kidneys healthy but may not always prevent kidney damage from occurring.

Prevention of Cardiovascular Problems and Complications

TRYZAN may be used to reduce the risk of some of the problems and complications that may arise in patients aged 55 or more who have problems such as coronary artery disease (heart disease caused by poor blood flow in the blood vessels of the heart), peripheral vascular disease (poor circulation in the hands or feet), or stroke.

TRYZAN may also be used to reduce the risk of cardiovascular problems and complications in patients with diabetes aged 55 years or more who may be considered at risk because of one or more additional factors such as high blood pressure, high cholesterol levels, kidney problems, a current smoker or previous disease of the blood vessels.

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.

TRYZAN is not recommended for use in children.

Safety and effectiveness in children have not been established.

2. What should I know before I take TRYZAN?

Warnings

Do not take TRYZAN if:

 you are allergic to ramipril, or any of the ingredients listed at the end of this leaflet. you have had an allergic reaction to any other ACE inhibitors previously.

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 on the skin

Do not take TRYZAN if you have ever taken any other ACE inhibitor medicine before, which caused your face, lips, tongue, throat, hands or feet to swell up, or made it hard for you to breathe.

If you have had an allergic reaction to an ACE inhibitor before, you may be allergic to TRYZAN.

Always check the ingredients to make sure you can take this medicine.

- you or your family have a history of swelling of the face, lips, tongue, throat, intestines, hands or feet, for no apparent reason
- you have kidney problems or a condition called 'renal artery stenosis'
- you have problems or conditions affecting the flow of blood in and out of your heart (e.g. aortic or valvular stenosis)
- you have low blood pressure
- you undergo dialysis using certain high-flux membranes

- you are diabetic or have kidney problems and are being treated with aliskiren-containing medicines or a group of medicines known as angiotensin II receptor antagonists AIIRAs (a medicine also used to treat high blood pressure)
- you are also currently taking sacubitril and valsartan for heart failure
- you are pregnant or intend to become pregnant
- you are breastfeeding
- the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

Check with your doctor if you:

- have allergies to any other medicines or other substances such as foods, preservatives or dyes
- have liver problems
- have low blood pressure, which you may notice as dizziness or lightheadedness
- have low white blood cell counts
- have high blood levels of potassium
- have certain types of autoimmune disorders, including Systemic Lupus Erythematosus (SLE), rheumatoid arthritis or scleroderma
- have any other medical conditions such as kidney problems or are having dialysis, heart problems or diabetes (note that your doctor may give you TRYZAN to treat these problems)
- are following a very low or very high salt diet
- are dehydrated or have had a recent bout of vomiting or diarrhoea

- are about to have surgery or a general anaesthetic
- plan to become pregnant or breastfeed.

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 taking TRYZAN.

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</u>. Are there any side effects?

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant. TRYZAN may affect your developing baby if you take it during pregnancy.

Talk to your doctor if you are breastfeeding or intend to breastfeed. TRYZAN may pass into breast milk and affect your baby.

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 TRYZAN and affect how it works. These include:

- other medicines used to treat high blood pressure, including those containing the active ingredient aliskiren
- other medicines used to treat heart failure
- diuretics, also known as fluid or water tablets
- lithium, a medicine used to treat mood swings and some types of depression
- potassium supplements or potassium-containing salt substitutes
- non-steroidal anti-inflammatory drugs (NSAIDs), medicines used to relieve pain, swelling and other symptoms of inflammation
- insulin and tablets used to treat diabetes
- heparin
- general anaesthetics
- medicines which may affect the blood cells, such as allopurinol, procainamide, corticosteroids, immunosuppressants, or medicines used to treat cancer
- temsirolimus
- Any medicines (including those available without a prescription) for appetite control, asthma, colds, coughs, hay fever, or sinus problems, if you are taking TRYZAN for high blood pressure. A discussion with your doctor or pharmacist should occur before using these while on TRYZAN.

These medicines may be affected by TRYZAN 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 taking this medicine.

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

4. How do I take TRYZAN?

How much to take

Your doctor or pharmacist will tell you how many tablets or capsules to take each day. This depends on your condition and whether you are taking any other medicines.

Take TRYZAN only when prescribed by your doctor.

TRYZAN is usually started at a low dose and then increased slowly.

Your doctor will select a dose when they prescribe TRYZAN for you. Some patients may need a lower starting dose.

The usual dose for TRYZAN is:

- for high blood pressure: 2.5 mg to 10 mg per day
- for heart failure: 5 mg to 10 mg per day
- for kidney problems: 1.25 mg to 5 mg per day
- for cardiovascular risk: 2.5 mg to 10 mg per day

Depending on your response, your doctor may adjust the dose. If two tablets are prescribed, your doctor may want you to take them both together or at different times. This will depend on the condition being treated and how you respond to TRYZAN.

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

How to take TRYZAN

 TRYZAN should be swallowed whole with plenty of fluid.

When to take TRYZAN

- TRYZAN should be taken at about the same time each day.
- Taking your tablets or capsules at the same time each day will have the best effect. It will also help you remember when to take your medicine.
- It does not matter if you take TRYZAN before or after food.

How long to take TRYZAN

Continue taking this medicine for as long as your doctor tells you.

This medicine helps control your condition but does not cure it. Therefore, TRYZAN must be taken every day.

If you forget to take TRYZAN

TRYZAN should be taken regularly at the same time each day.

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Otherwise, take it as soon as you remember, and then go back to taking your medicine as you would normally.

Do not take a double dose to make up for the dose you missed.

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

 If you are not sure what to do, ask your doctor or pharmacist. If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

If you take too much TRYZAN

If you think that you or anyone else has taken too much TRYZAN, urgent medical attention may be needed.

You should immediately:

- phone the Poisons Information Centre (Australia telephone 13 11 26) for advice, 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.

If you take too much TRYZAN, you may feel dizzy, lightheaded or you may faint. You may also experience slow heartbeat.

5. What should I know while taking TRYZAN?

Things you should do

- Stand or get up slowly, especially from bed or chairs, will help your body get used to the change in position and blood pressure. This will help reduce feeling lightheaded, dizzy, or faint.
- Drink enough water during exercise and hot weather when you are taking TRYZAN, especially if you sweat a lot. If you do not drink enough water, you may feel light-headed, dizzy, or faint. This is because your blood pressure is dropping suddenly. If you continue to feel unwell, tell your doctor.
- If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking TRYZAN.
- Remind any doctor, dentist, or pharmacist you visit that you are using TRYZAN.
- If you plan to have surgery that needs a general anaesthetic, tell your doctor or dentist you are taking TRYZAN.

Your blood pressure may drop suddenly.

- If you are about to have any blood tests, tell the doctor that you are taking TRYZAN.
 It may interfere with the results of some tests.
- Have your blood pressure checked when your doctor says, to make sure TRYZAN is working.
- Keep all of your doctor's appointments so that your progress can be checked.

Your doctor may occasionally do a blood test to check your potassium levels and see how your kidneys are working.

Call your doctor straight away if you

- have excess vomiting or diarrhoea while taking TRYZAN. You may lose too much water and salt from your body, which can cause your high blood pressure to drop too much.
- feel light-headed or dizzy after taking your first dose of TRYZAN, or when your dose is increased.
- become pregnant or intend to become pregnant while taking TRYZAN.

Things you should not do

- Give TRYZAN to anyone else, even if they have the same condition as you.
- Take TRYZAN to treat any other complaints unless your doctor or pharmacist tells you to.
- Stop taking or lower/increase the dosage without checking with your doctor.

Driving or using machines

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

As with other ACE inhibitor medicines, TRYZAN may cause light-headedness, dizziness, or drowsiness in some people.

Make sure you know how you react to TRYZAN before you drive a car, operate machinery, or do anything else that could be dangerous if you are dizzy or light-headed. If this occurs do not drive.

Drinking alcohol

Tell your doctor if you drink alcohol.

If you drink alcohol while taking TRYZAN, your dizziness, drowsiness, or light-headedness may be worse.

Things that may help your condition

Some self-help measures suggested below may help your condition. Talk to your doctor or pharmacist about these measures for more information.

Alcohol - your doctor may advise you to limit your alcohol intake.

 Diet - eat a healthy low-fat diet which includes plenty of fresh vegetables, fruit, bread, cereals, and fish. Reduce intake of foods with a high fat or sugar content.

- Exercise regular exercise helps to reduce blood pressure and helps to get the heart fitter, but it is also important not to overdo it. Walking is a good exercise but try to find a route that is reasonably flat. Before starting any exercise, ask your doctor about the best kind of exercise program for you.
- Salt your doctor may advise you to watch the amount of salt in your diet. To reduce your salt intake, you should avoid using salt in cooking or at the table.
- Smoking your doctor may advise you to stop or at least cut down on smoking.
- Weight your doctor may suggest losing some weight to help lower your blood pressure and help lessen the amount of work your heart has to do. Some people may need a dietician's help to lose weight.

Looking after your medicine

- Keep your TRYZAN tablets or capsules in the blister pack until it is time to take them. If you take them out of the pack they may not keep well.
- Store below 25°C.

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

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

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

Heat and dampness can destroy some medicines.

Keep it where young children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Getting rid of any unwanted medicine

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

Do not take this medicine after the expiry date.

6. Are there any side effects?

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking TRYZAN.

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.

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

Less serious side effects

Less serious side effects	What to do
 feeling light-headed, dizzy or faint dry cough headache 	Speak to your doctor if you have any of these less serious side effects and they worry you.
 feeling sick (nausea) or vomiting stomach pain or discomfort diarrhoea indigestion loss or taste, or taste disturbances upper respiratory tract infections muscle cramps or spasms aching muscles, muscle tenderness or weakness unrelated to exercise unusual tiredness or weakness, fatigue ringing or buzzing in the ears 	These side effects are common, and usually mild.
forgetfulness or confusion	

Serious side effects

Serious side effects	What to do
 disturbed vision symptoms of sunburn (such as redness, itching, swelling, blistering) which may occur more quickly than normal 	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.
 itchy or raised skin rash, hives or nettle rash signs of anaemia such as tiredness, being short of breath and looking pale 	These side effects are rare.
 yellowing of the skin and/or eyes fast or irregular heartbeat 	
 shortness of breath or tightness in the chest numbness, tingling and colour change (white, blue then red) in the fingers or toes when exposed to the cold 	

Serious side effects	What to do
 severe upper stomach pain, often with nausea and vomiting 	
 frequent infections such as fever, severe chills, sore throat or mouth ulcers 	
 passing little or no urine or more urine than is normal for you 	
 bleeding or bruising more easily than normal 	

Very serious side effects

Very serious side effects	What to do
 fainting within a few hours of taking a dose severe dizziness and confusion with visual disturbances and speech problems 	Go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.
 swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing 	These side effects are very rare.

Very serious side effects	What to do
 pink or red itchy spots on the skin which may blister and progress to form raised, red, pale- centred marks 	
 severe blisters and bleeding in the lips, eyes, mouth, nose and genitals chest pain 	

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 www.tga.gov.au/reporting-problems. 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 TRYZAN contains

Active ingredient (main ingredient)	Ramipril 1.25 mg, 2.5 mg, 5 mg or 10 mg
Other ingredients (inactive ingredients)	 TRYZAN CAPS also contain pregelatinised maize starch 1.25 mg: Empty Hard Gelatin capsule size 4 White/Yellow #G41CSRR0495 (ID 107565) 2.5 mg: Empty Hard Gelatin Capsule Size 4 White/Orange #G41CSRR0494 (ID 107558) 5 mg: Empty Hard Gelatin Capsule Size 4 White/Swedish Orange #G41CSRR0493 (ID 107560)

	 10 mg: Empty Hard Gelatin Capsule Size 4 White/Blue #G41CSRR0496 (ID 107564) Opacode Black S-1-8114/S-1-8115 (ID 2328) TRYZAN TABS also contain
	 sodium bicarbonate lactose monohydrate pregelatinised maize starch croscarmellose sodium sodium stearylfumarate Pigment blend PB-22960 (ID 12073) (2.5 mg tablet) Pigment blend PB-24877 (ID 12074) (5 mg tablet)
Potential allergens	TRYZAN CAPS contain phenylalanine and sulfites. TRYZAN TABS contain sugars as lactose.

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

What TRYZAN looks like

TRYZAN is available in four different strengths. TRYZAN capsules or tablets are available in 1.25 mg, 2.5 mg, 5 mg or 10 mg.

TRYZAN CAPS:

TRYZAN CAPS 1.25 mg are white and yellow capsule; the body has 'G' and the cap has 'RM 1.25' printed in black ink. Capsules contain a white to off-white powder. (AUST R 127085).

TRYZAN CAPS 2.5 mg are white and orange capsule; the body has 'G' and the cap has 'RM 2.5' printed in black ink. Capsules contain a white to off-white powder. (AUST R 127088).

TRYZAN CAPS 5 mg are white and Swedish orange capsule; the body has 'G' and the cap has 'RM 5' printed in black ink. Capsules contain a white to off-white powder. (AUST R 127152).

TRYZAN CAPS 10 mg are white and blue capsule; the body has 'G' and the cap has 'RM 10' printed in black ink. Capsules contain a white to off-white powder. (AUST R 127153).

Each pack contains 30 capsules.

TRYZAN TABS:

TRYZAN TABS 1.25 mg are white to off-white, capsule-shaped, un-coated, flat and unmarked. (AUST R 129873).

TRYZAN TABS 2.5 mg are yellow, capsule-shaped, uncoated, flat, scored on one side and side walls, marked R2. (AUST R 129916).

TRYZAN TABS 5 mg are pink, capsule-shaped, uncoated, flat, scored on one side and side walls, marked R3. (AUST R 129918).

TRYZAN TABS 10 mg are white to off-white, capsule-shaped, un-coated, flat, scored on one side and side walls, marked R4. (AUST R 129921).

Each pack contains 30 tablets.

Who distributes TRYZAN

Alphapharm Pty Ltd trading as Viatris

Level 1, 30 The Bond

30-34 Hickson Road

Millers Point NSW 2000

www.viatris.com.au

Phone: 1800 274 276

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