

TRYZAN CAPS; TRYZAN TABS

ramipril

CONSUMER MEDICINE INFORMATION

What is in this leaflet

This leaflet answers some common questions about TRYZAN.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have benefits and risks. Your doctor has weighed the risks of you taking TRYZAN against the benefits expected for you.

If you have any concerns about taking this medicine, talk to your doctor or pharmacist.

Keep this leaflet with your medicine.

You may need to read it again.

What TRYZAN is used for

TRYZAN contains the active ingredient ramipril. It belongs to a group of medicines called angiotensin converting enzyme (ACE) inhibitors.

TRYZAN is used to treat:

- high blood pressure (hypertension)
- some heart conditions such as heart failure after a heart attack
- kidney problems in some patients

TRYZAN is also used to reduce the risk of cardiovascular problems and complications in patients aged 55 years or more with heart or blood vessel disease, or diabetes.

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 after 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.

How TRYZAN works

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.

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.

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

This medicine is not addictive.

Before you take TRYZAN

When you must not take it

Do not take TRYZAN if you have had an allergic reaction to:

- any medicine containing ramipril or another ACE inhibitor
- any of the ingredients listed at the end of this leaflet

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.

Do not take TRYZAN if you or your family have a history of swelling of the face, lips, tongue, throat, intestines, hands or feet, for no apparent reason.

Do not take TRYZAN if you have or have had any of the following medical conditions:

- kidney problems or a condition called 'renal artery stenosis'
- problems or conditions affecting the flow of blood in and out of your heart (e.g. aortic or valvular stenosis)
- low blood pressure

Do not take this medicine if you undergo dialysis using certain high-flux membranes.

Do not take this medicine if you are a diabetic or have kidney problems and are being treated with aliskiren-containing medications or a group of medicines known as AIIRAs (a medicine also used to treat high blood pressure).

Do not take this medicine if you are also currently taking sacubitril and valsartan (Entresto®) for heart failure.

Do not take this medicine if you are pregnant or plan to become pregnant.

It may affect your developing baby if you take it during pregnancy.

Tell your doctor if you are breastfeeding or wish to breastfeed.

TRYZAN may pass into breast milk and affect your baby.

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

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

If you are not sure whether you should start taking this medicine, talk to your doctor.

Before you start to take it

Tell your doctor if you are allergic to any other medicines, foods, dyes or preservatives.

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

- kidney problems or are having dialysis (note that your doctor may give you TRYZAN because of your kidney problems)
- liver problems

- heart problems (note that your doctor may give you TRYZAN because of your heart problems)
- low blood pressure, which you may notice as dizziness or light-headedness
- low white blood cell counts
- diabetes (note that your doctor may give you TRYZAN because of your diabetes).
- high levels of potassium in your blood
- certain types of autoimmune disorders, including Systemic Lupus Erythematosus (SLE), rheumatoid arthritis and scleroderma

You must also tell your doctor if you:

- are following a very low or very high salt diet
- are dehydrated, or have had a recent bout of vomiting or diarrhoea
- are going 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.

Taking other medicines

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

Some medicines and TRYZAN may interfere with each other. 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

If you are taking TRYZAN for high blood pressure, do not take any medicines (including the ones bought without a prescription) for appetite control, asthma, colds, coughs, hayfever or sinus problems unless you have discussed it with your doctor or pharmacist.

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.

How to take TRYZAN

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

They may differ from the information contained in this leaflet.

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

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 of 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

Your doctor may adjust the dose depending on your condition and the way you respond to TRYZAN.

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

How to take it

Swallow the tablets or capsules whole with a glass of water.

When to take it

Take your medicine at about the same time each day.

Taking it at the same time each day will have the best effect. It will also help you remember when to take it.

It does not matter if you take your medicine before or after food.

How long to take it

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 it

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 (overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26) for advice, or go to Accident and Emergency at the nearest hospital, if you think you or anyone else may have taken too much TRYZAN.

Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

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

While you are taking TRYZAN

Things you must do

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

Tell any other doctors, dentists and pharmacists who are treating you that you are taking this medicine.

Make sure you 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 while taking TRYZAN, you may feel faint, light-headed or sick. This is because your blood pressure is dropping suddenly. If you continue to feel unwell, tell your doctor.

If you have excess vomiting or diarrhoea while taking TRYZAN, tell your doctor.

You may lose too much water and salt and your blood pressure may drop too much.

If you feel light-headed or dizzy after taking your first dose of TRYZAN, or when your dose is increased, tell your doctor immediately.

If you going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine.

Your blood pressure may drop suddenly.

If you become pregnant or intend to become pregnant while taking TRYZAN, tell your doctor immediately.

If you are about to have any blood tests, tell your doctor that you are taking this medicine.

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.

Things you must not do

Do not take TRYZAN to treat any other complaints unless your doctor tells you to.

Do not give your medicine to anyone else, even if they have the same condition as you.

Do not stop taking your medicine, or lower or increase the dosage, without checking with your doctor.

Things to be careful of

If you feel light-headed, dizzy or faint when getting out of bed or upon standing up, get up slowly.

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.

Be careful driving or operating machinery until you know how TRYZAN affects you.

As with other ACE inhibitor medicines, TRYZAN may cause dizziness, light-headedness, tiredness 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. If you drink alcohol, dizziness 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, fruits, bread, cereals and fish. Also eat less fat and sugar
- exercise - regular exercise helps to reduce blood pressure and helps get the heart fitter, but it is important to not overdo it. Walking is good exercise, but try to find a route that is reasonably flat. Before starting any exercise regimen, ask your doctor first
- 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

Side effects

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

This medicine helps most people, but it may have unwanted side effects in some people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Do not be alarmed by the following list 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 if you notice any of the following and they worry you:

- feeling light-headed, dizzy or faint
- dry cough
- headache
- feeling sick (nausea) or vomiting

- stomach pain or discomfort
- diarrhoea
- indigestion
- loss of taste or taste disturbances
- upper respiratory tract infections
- muscle cramps or spasms
- aching muscles, muscle tenderness or weakness, not caused by exercise
- unusual tiredness or weakness, fatigue
- ringing or buzzing in the ears
- forgetfulness or confusion

These side effects are usually mild.

Tell your doctor as soon as possible if you notice any of the following:

- disturbed vision
- symptoms of sunburn (such as redness, itching, swelling, blistering) which may occur more quickly than normal
- itchy or raised skin rash, hives or nettlerash
- signs of anaemia such as tiredness, being short of breath and looking pale

- yellowing of the skin and/or eyes
- fast or irregular heart beat
- 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
- 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

These may be serious side effects that may require medical attention. Serious side effects are rare.

If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- fainting within a few hours of taking a dose
- severe dizziness and confusion with visual disturbances and speech problems
- swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing

- 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

These are very serious side effects. You may need urgent medical attention or hospitalisation. These side effects are very rare.

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.

After taking TRYZAN

Storage

Keep your medicine in the pack until it is time to take them.

If you take the medicine out of the pack they will not keep well.

Keep your medicine in a cool dry place where the temperature stays below 25°C.

Do not store TRYZAN or any other medicine in the bathroom or near a sink. Do not leave it in the car or on a window sill.

Heat and dampness can destroy some medicines.

Keep TRYZAN where children cannot reach it.

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

Disposal

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

Product description

What it looks like

TRYZAN CAPS

TRYZAN CAPS come in four strengths of capsules:

- TRYZAN CAPS 1.25 - white and yellow capsule; the body has 'G' and the cap has 'RM 1.25' printed in black ink
- TRYZAN CAPS 2.5 - white and orange capsule; the body has 'G' and the cap has 'RM 2.5' printed in black ink
- TRYZAN CAPS 5 - white and Swedish orange capsule; the body has 'G' and the cap has 'RM 5' printed in black ink
- TRYZAN CAPS 10 - white and blue capsule; the body has 'G' and the cap has 'RM 10' printed in black ink

Each pack contains 30 capsules.

TRYZAN TABS

TRYZAN TABS come in four strengths of tablets:

- TRYZAN TABS 1.25 - white to off-white, capsule-shaped, un-coated, flat and unmarked
- TRYZAN TABS 2.5 - yellow, capsule-shaped, un-coated, flat, scored on one side and side walls, marked R2
- TRYZAN TABS 5 - pink, capsule-shaped, un-coated, flat, scored on one side and side walls, marked R3
- TRYZAN TABS 10 - white to off-white, capsule-shaped, un-coated, flat, scored on one side and side walls, marked R4

Each pack contains 30 tablets.

Ingredients

TRYZAN CAPS

- each TRYZAN CAPS 1.25 capsule contains 1.25 mg of ramipril
- each TRYZAN CAPS 2.5 capsule contains 2.5 mg of ramipril
- each TRYZAN CAPS 5 capsule contains 5 mg of ramipril

- each TRYZAN CAPS 10 capsule contains 10 mg of ramipril

The capsules also contain the following inactive ingredients:

- pregelatinised maize starch
- gelatin
- titanium dioxide
- FDA/E172 yellow iron oxide (1.25 mg and 2.5 mg capsules)
- EEC Erythrosine E127 (2.5 mg, 5 mg and 10 mg capsules)
- indigo carmine (5 mg and 10 mg capsules)
- FDA/E172 Black Iron Oxide (10 mg capsule)
- TekPrint SW-9008 Black Ink (PI # 2328)
- TekPrint SW-9009 Black Ink (PI # 2343)

TRYZAN CAPS are gluten free.

TRYZAN TABS

- each TRYZAN TABS 1.25 tablet contains 1.25mg of ramipril
- each TRYZAN TABS 2.5 tablet contains 2.5 mg of ramipril

- each TRYZAN TABS 5 tablet contains 5 mg of ramipril
- each TRYZAN TABS 10 tablet contains 10 mg of ramipril

The tablets also contain the following inactive ingredients:

- sodium bicarbonate
- lactose
- pregelatinised maize starch
- croscarmellose sodium
- sodium stearyl fumarate
- Pigment blend PB-22960 (PI # 12073) (2.5 mg tablet)
- Pigment blend PB-24877 (PI # 12074) (5 mg tablet)

TRYZAN TABS do not contain gluten.

Supplier

TRYZAN is supplied by:

Alphapharm Pty Limited

(ABN 002 359 739)

Level 1 30 The Bond

30-34 Hickson Road

Millers Point NSW 2000

Phone: (02) 9298 3999

www.mylan.com.au

Australian registration numbers:

TRYZAN CAPS

TRYZAN CAPS 1.25: AUST R 127085

TRYZAN CAPS 2.5: AUST R 127088

TRYZAN CAPS 5: AUST R 127152

TRYZAN CAPS 10: AUST R 127153

TRYZAN TABS

TRYZAN TABS 1.25: AUST R 129873

TRYZAN TABS 2.5: AUST R 129916

TRYZAN TABS 5: AUST R 129918

TRYZAN TABS 10: AUST R 129921

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