NEW ZEALAND CONSUMER MEDICINE INFORMATION

TRYZAN

Ramipril capsule 1.25, 2.5, 5 & 10 mg

What is in this leaflet

Please read this leaflet carefully before you start taking Tryzan.

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 risks and benefits. Your doctor has weighed the risks of you taking Tryzan against the benefits they expect it will have for you.

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

Keep this leaflet with the medicine. You may need to read it again.

What Tryzan is used for

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

Tryzan is also used to reduce the riskof 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 heart attack and does not mean that the heart stops. Heart failure may start off with no symptoms, but as conditions progresses, patient 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 preventkidney 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 poorblood flow in the blood vessels of theheart), 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, acurrent smoker, or previous disease of the blood vessels.

How Tryzan works

Tryzan works by widening the bloodvessels, 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 betterand 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 riskof 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 thekidneys to work more efficiently. This in turn can help to slow downthe progression of kidney damage that might result from having diabetes or high blood pressure.

Therefore, there are quite a few reasons why your doctor might havedecided to treat you with Tryzan.

Your doctor may have also prescribed this medicine for another reason.

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

Tryzan is not addictive.

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

Before you take Tryzan

When you must not take it

Do not take Tryzan if you have an allergy to:

- any medicine containing ramipril, or an 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. have 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.

- Or your family have a history of swelling of the face, lips, tongue, throat, intestines, hands or feet, for no apparent reason.
- Have kidney problems or a condition called 'renal artery stenosis'.
- Have problems or conditions affecting the flow of blood in and out of your heart (e.g. aortic or valvular stenosis).
- Have low blood pressure.
- Undergo dialysis using certain high-flux membranes.
- Are diabetic or have kidney problems and are being treated with aliskiren-containing medicines 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 pregnant.

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

Do not breast-feed if you are taking this medicine.

The active ingredient in Tryzan passes into breast milk (if applicable) and there is a possibility that your baby may be affected.

Do not give this medicine to a child under the age of 18 years. Safety and effectiveness in children younger than 18 years have not been established.

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 have allergies to any other medicines, foods, preservatives or dyes.

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 yourblood.
- Systemic Lupus Erythematosus(SLE), scleroderma or other autoimmune conditions

Tell your doctor if you have a family history of swelling of the face, lips, tongue, throat, intestines, hands or feet.

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 about to have surgery or general anaesthetic.

Tell your doctor if you are pregnant or plan to become pregnant or are breast-feeding. 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 medicines that you buy without a prescription from your pharmacy, supermarket or health food shop.

You should also tell any health professional who is prescribing a new medication for you that you are taking Tryzan.

Some medicines may interfere with Tryzan. 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 treatmood swings and some types ofdepression
- potassium supplements or potassium-containing salt substitutes
- non-steroidal anti-inflammatory drugs (NSAIDs), medicines used to relieve pain, swelling and othersymptoms 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) forappetite 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 or pharmacist carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the [box/bottle], ask your doctor or pharmacist for help.

How much to take

Your doctor or pharmacist will tell you how many capsules you will need to take each day. This depends on your condition and whether or not you are taking any other medicine.

Take Tryzan only when prescribed by your doctor.

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 5mg per day.
- for cardiovascular risk, 2.5 mg to 10 mg per day.

Depending on your response, yourdoctor 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 toTryzan.

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 box, ask yourdoctor or pharmacist for help.

How to take it

Swallow the capsules whole with a full 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 this medicine before or after food.

How long to take it

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

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

Continue taking your medicine until you finish the pack.

Stop using this medicine when the redness and itching have gone.

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 that 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.

While you are taking Tryzan

Things you must do

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

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

If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine. It may affect other medicines used during surgery.

Your blood pressure may drop suddenly.

Make sure you drunk 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 excessive 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 become pregnant while taking this medicine, 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 check your potassium levels and see how your kinds are working from time to time to make sure the medicine is working and to prevent unwanted side effects.

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 the dosage without checking with your doctor. If you stop taking it suddenly, your condition may worsen or you may have unwanted side effects.

If possible, your doctor will gradually reduce the amount you are taking each day before stopping the medicine completely.

Things to be careful of

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 lightheaded. If this occurs do not drive.

Be careful when drinking alcohol while you are taking this medicine.

If you drink alcohol, dizziness or light-headedness may be worse.

If you feel light-headed, dizzy or faint when getting out of bed or 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.

Things that would be helpful for your condition

Some self help measures suggested below may help your condition. Your doctor or pharmacist can give you more information about these measures.

- 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. Also eat less fat and sugar.
- Exercise regular exercise helps to reduce blood pressure and helps get the heart fitter, but it is important not to overdo it. Walking is good exercise, but tryto find a route that is reasonably flat. Before starting any exercise, ask your doctor about the best kind of programme for you.
- Salt your doctor may advise youto watch the amount of salt in your diet. To reduce your salt intake you should avoid using saltin cooking or at the table.
- Smoking your doctor may advise you to stop or at least cutdown smoking.
- Weight your doctor may suggestlosing some weight to help lower your blood pressure and help lessen the amount of work your heart has to do.
 Some people mayneed a dietician's help to lose weight.

In case of overdose

If you take too much (overdose) Immediately telephone your doctor or the National Poisons Centre (telephone 0800 POISON or 0800 764 766), or go to accident and emergency at your nearest hospital, if you think that 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 light-headedness, dizzy or you may faint. You may also experience slow heart beat.

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 with hypertension, 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 treatment if you get some of the side effects.

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

Tell your doctor or pharmacist 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

The above list includes the more common side effects of your medicine. They 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 morequickly than normal
- itchy or raised skin rash, hives ornettlerash
- 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 inthe chest
- numbness, tingling and colour change (white, blue then red) in the fingers or toes when exposed to the cold
- severe upper stomach pain, oftenwith nausea and vomiting
- frequent infections such as fever, severe chills, sore throat or mouthulcers
- passing little or no urine or moreurine than is normal for you
- bleeding or bruising more easilythan normal

The above list includes 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 causedifficulty in swallowing or breathing
- pink or red itchy spots on the skinwhich may blister and

progress toform raised, red, pale-centred marks

- severe blisters and bleeding in thelips, eyes, mouth, nose and genitals
- chest pain

The above list includes 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. Tell your doctor if you notice any other effects.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

After taking Tryzan

Storage

Keep your capsules in the pack until it is time to take them. If you take the capsules out of the pack they may not keep well.

Keep your capsules 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 on a window sill or in the car.

Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.

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

Disposal

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.

Product description

What it looks like

Tryzan 1.25 mg: Hard gelatin capsule with white opaque body and yellow opaque cap. The body has "G" and the cap has "RM 1.25" both printed in black. Capsules contain a white to off-white powder.

Tryzan 2.5 mg: Hard gelatin capsule with white opaque body and orange opaque cap. The body has "G" and the cap has "RM 2.5" both printed in black. Capsules contain a white to off-white powder.

Tryzan 5 mg: Hard gelatin capsule with white opaque body and Swedish orange opaque cap. The body has "G" and the cap has "RM 5" both printed in black. Capsules contain a white to off-white powder.

Tryzan 10 mg: Hard gelatin capsule with white opaque body and blue opaque cap. The body has "G" and the cap has "RM 10" both printed in black. Capsules contain a white to off-white powder.

Ingredients

Active ingredient: Tryzan contains 1.25, 2.5, 5 & 10 mg of ramipril as the active ingredient.

<u>Inactive ingredients:</u> Tryzan also contains:

- Starch pregelatinised
- Titanium dioxide
- Gelatin
- Yellow iron oxide (1.25 & 2.5 mg)
- FD&C Red #3 (2.5, 5 & 10 mg)
- FD&C Blue #2 (5 & 10 mg)
- Black iron oxide (10 mg)

Contains phenylalanine and sulfites.

If you want to know more

Should you have any questions regarding this product, please contact your pharmacist or doctor.

Who supplies this medicine

Tryzan is supplied in New Zealand by:

Viatris Ltd PO Box 11-183 Ellerslie AUCKLAND <u>www.viatris.co.nz</u> Telephone 0800 168 169

Date of Preparation

14 February 2023. (Based on datasheet dated 14 February 2023)