

Tryzan

contains the active ingredient 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 is used to treat:

- * high blood pressure (hypertension)
- * heart failure

Tryzan is also used to help:

- * reduce the risk of having a heart attack, stroke, or death due to heart disease, in some people
- * slow down the progression of kidney disease

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

Your doctor may have prescribed Tryzan for another purpose.

How Tryzan works

Tryzan belongs to a group of medicines called angiotensin converting enzyme (ACE) inhibitors.

ACE inhibitors lower blood pressure by widening blood vessels, making it easier for the heart to pump blood around the body.

Widening of the blood vessels also increases the supply of blood and oxygen to the heart. By increasing the supply of oxygen to your heart, your heart does not have to work as hard.

If you have heart failure, this helps by allowing your heart to cope better when you place extra demands on it, such as during exercise, so you may not get short of breath as easily.

By keeping your blood vessels and heart muscle healthy, Tryzan also reduces the risk of having a heart attack, stroke, or death due to heart disease if you are older than 55 years of age and you have, or have had the following:

- * heart or blood vessel problems, or stroke
- * diabetes and one other risk factor, such as high blood pressure, high levels of cholesterol in your blood, certain types of kidney problems, or a history of blood vessel problems

If you have kidney problems, Tryzan slows down worsening of the illness by lowering the blood pressure and by helping to keep kidney cells healthy.

Tryzan is not recommended for use in children.

Safety and effectiveness of Tryzan in children have not been clearly established.

Tryzan is available only with a doctor's prescription.

There is no evidence that Tryzan is addictive.

Before you take Tryzan

When you must not take it

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

- * medicines containing ramipril
- * any of the ingredients listed at the end of this leaflet

Some of the symptoms of an allergic reaction may include skin rash, itching or hives, swelling of the face, lips, mouth, throat or other parts of the body, shortness of breath, wheezing or troubled breathing.

Do not take Tryzan if you have ever taken any other ACE inhibitor medicine, 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 could be allergic to Tryzan.

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

- * hereditary angioedema
- * idiopathic angioedema

Angioedema is a swelling of the face, lips, tongue, throat, hands or feet, and/or severe, painful or repeated abdominal cramps with vomiting; these can occur following exposure to a known trigger, or for no apparent reason.

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

Tryzan is not recommended for use during pregnancy. Your doctor will discuss the risks and benefits of taking Tryzan during pregnancy.

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

Tryzan may pass into breast milk. It is recommended that you do not breastfeed while taking Tryzan.

Check with your doctor or pharmacist if you are not sure about any of the above.

Do not take Tryzan if the expiry date (EXP.) printed on the pack has passed.

If you take this medicine after the expiry date, it may not work as well.

Do not take Tryzan if the packaging shows signs of tampering or the capsules do not look quite right.

Before you start to take it

Be sure to tell your doctor if you have had any type of allergic reaction to an ACE inhibitor.

You may have an increased chance of being allergic to Tryzan if you are allergic to other ACE inhibitors.

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

Tell your doctor if you are having dialysis or plan to have surgery.

Tell your doctor if you have high blood cholesterol levels and are undergoing a procedure known as lipoprotein apheresis.

Tell your doctor if you have, or have had, any other health problems or medical conditions,

especially the following:

- * kidney problems
- * heart problems, including angina (chest pain), heart failure, or a heart attack
- * stroke or any other condition that affects the blood vessels of the brain
- * blood pressure problems, or are taking medication for blood pressure
- * liver problems
- * recent bouts of diarrhoea or vomiting
- * certain types of autoimmune disorders, including Systemic Lupus Erythematosus (SLE), rheumatoid arthritis and scleroderma
- * diabetes

If you have not told your doctor about any of the above, tell him/her before you start taking Tryzan.

If you have these conditions, your doctor may want to ask you more questions to see if Tryzan is suitable for you, or else he/she may want to take special care or adjust your dose.

Taking other medicines

Tell your doctor 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 may be affected by Tryzan, or may affect how well it works. These include:

- * other medicines used to treat high blood pressure, or other heart and kidney disorders
- * fluid tablets (diuretics), such as indapamide (e.g. Natrilix, Dapa-tabs), frusemide (e.g. Lasix, Uremide), amiloride (Kaluril, Midamor, and found in Moduretic and Amizide), triamterene (found in Hydrene) and spironolactone (Aldactone, Spiractin)
- * potassium supplements (e.g. Slow-K) or potassium-containing

salt substitutes

- * lithium (Lithicarb), a medicine used to treat mood swings and some types of depression
- * non-steroidal anti-inflammatory medicines (NSAIDs), medicines used to relieve pain, swelling and other symptoms of inflammation, such as indomethacin (Indocid, Arthrexin), naproxen (e.g. Naprosyn, Inza) and diclofenac (e.g. Voltaren, Fenac)
- * medicines used to treat diabetes
- * allopurinol (e.g. Zyloprim, Progot), a medicine used to prevent gout
- * immunosuppressants such as azathioprine (e.g. Imuran, Thioprine), cyclosporin (e.g. Neoral, Sandimmun) and tacrolimus (Prograf), medicines used to help prevent organ transplant rejection or to treat certain problems with the immune system
- * anticholinergics, found in some medicines used to relieve or treat stomach cramps, travel sickness, hayfever and allergies, cough and colds and depression

Your doctor can tell you what to do if you are taking any of these medicines.

If you are not sure whether you are taking any of these medicines, check with your doctor or pharmacist.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking Tryzan.

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.

How much to take

The dose varies from person to person.

Your doctor will tell you how much Tryzan you need to take each day.

Ask your doctor or pharmacist for help if you do not understand the instructions on the label.

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

For the treatment of high blood pressure or heart failure, and for helping reduce the risk of having a heart attack, stroke, or death due to heart disease, the maximum dose is usually 10 mg, taken in single or divided doses.

When Tryzan is taken to slow down the progression of kidney disease, the maximum dose is usually 5 mg per day.

However, your doctor may ask you to take a different dose, depending on your condition and the way you respond to Tryzan.

How to take Tryzan

Swallow the capsules whole with a glass of water, before, during or after meals.

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.

If you forget to take Tryzan

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 capsules 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 miss more than one dose, or

are not sure what to do, ask your doctor or pharmacist.

How long to take Tryzan for

Keep taking Tryzan for as long as your doctor recommends.

Tryzan helps control your condition, but does not cure it. Therefore Tryzan must be taken every day for as long as your doctor recommends.

If you take too much Tryzan (overdose)

Immediately telephone your doctor, or the Poisons Information Centre (telephone 13 11 26), 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 very dizzy, light-headed, weak or faint.

While you are taking Tryzan

Things you must do

Tell all the doctors, dentists and pharmacists who are treating you that you are taking Tryzan.

Before starting any new medicine, tell your doctor or pharmacist that you are taking Tryzan.

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

If you plan to have surgery, including dental surgery, which requires an anaesthetic, tell your doctor or dentist that you are taking Tryzan.

Your doctor or dentist may advise you to temporarily stop taking Tryzan before surgery to avoid a sudden drop in your blood pressure during the procedure.

If you have to have any blood or urine tests, tell your doctor that you are taking Tryzan.

Tryzan may affect the results of some tests.

If you develop swelling of the face, lips, tongue, throat, hands or feet, and/or severe, painful or repeated abdominal cramps with vomiting while taking Tryzan, or up to several weeks after stopping Tryzan, tell your doctor immediately.

This may mean that you are suffering from an allergy to Tryzan. You may need urgent medical attention.

During hot weather, or if you exercise or sweat a lot, make sure you drink enough water.

If you do not drink enough water while taking Tryzan, you may feel faint, lightheaded or sick. This is because your body does not have enough fluid and your blood pressure is low. If you continue to feel unwell, tell your doctor.

If you have severe vomiting or diarrhoea while taking Tryzan, tell your doctor.

This may cause you to lose too much water and salt, and your blood pressure may become too low.

Keep all of your appointments with your doctor.

Your doctor may want to take additional tests to monitor your progress and your response to Tryzan.

Things you must not do

Do not stop taking Tryzan, or lower the dose, unless advised to by your doctor.

Do not use Tryzan to treat any other conditions unless advised to by your doctor.

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

Things to be careful of

Be careful getting up from a sitting or lying position.

Dizziness, lightheadedness or fainting may occur, especially if you get up too quickly. This is more likely to occur when you start taking Tryzan, or if the dose is increased. Getting up slowly may help.

If these symptoms continue or become worse, tell your doctor.

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

Tryzan may cause dizziness or lightheadedness in some people. If this occurs, do not drive, operate machinery or do anything else that could be dangerous.

Side effects

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

Tryzan helps most people, but it may have unwanted side effects in some people. 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 this list of possible 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:

- * nausea
- * dizziness or feeling tired
- * headache
- * dry, persistent cough
- * changes in taste

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

- * signs of frequent infections such as fever, chills, sore throat or

mouth ulcers

- * bleeding or bruising more easily than normal
- * skin rash, with or without fever and joint pain
- * yellowing of the skin and/or eyes (jaundice)
- * passing little or no urine, or more urine than usual
- * signs of a high potassium level, such as:
 - confusion, nervousness
 - numbness or tingling in the hands, feet or lips
 - weakness or heaviness in the legs

Stop taking Tryzan and tell your doctor immediately or go to casualty at the nearest hospital if any of the following happen:

- * fainting within a few hours of taking a dose
- * swelling of the face, lips, tongue or throat which may cause difficulty in swallowing or breathing
- * swelling of the hands or feet
- * painful or repeated stomach cramps with or without vomiting
- * fast or irregular heart beat
- * shortness of breath or tightness in the chest
- * pink or red itchy spots on the skin which may blister and progress to form raised, red, pale-centred marks
- * blisters or bleeding in the lips, eyes, mouth, nose and genitals

Tell your doctor 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 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.

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

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

Keep Tryzan in a cool dry place where the temperature stays below 25 degrees C.

Do not keep Tryzan or any other medicine in the bathroom or near a sink.

Do not leave Tryzan in the car or on window sills.

Heat and dampness can destroy some medicines.

Disposal

If your doctor tells you to stop taking Tryzan, or your medicine has passed its expiry date, ask your pharmacist what to do with any capsules that are left over.

Product description

What it looks like

Tryzan comes in four strengths of capsules:

- * Tryzan 1.25 - yellow capsule; the body has 'G' and the cap has 'RM 1.25' printed in black ink
- * Tryzan 2.5 - orange capsule; the body has 'G' and the cap has 'RM 2.5' printed in black ink
- * Tryzan 5 - red capsule; the body has 'G' and the cap has 'RM 5' printed in black ink
- * Tryzan 10 - blue capsule; the body has 'G' and the cap has 'RM

10' printed in black ink.

Each pack contains 30 capsules.

Tryzan is also available as a Titration Pack. Each Tryzan titration pack contains the following:

- * 7 capsules of Tryzan 2.5
- * 21 capsules of Tryzan 5
- * 10 capsules of Tryzan 10

Ingredients

The active ingredient in Tryzan is ramipril

- * each Tryzan 1.25 capsule contains 1.25 mg of ramipril
- * each Tryzan 2.5 capsule contains 2.5 mg of ramipril
- * each Tryzan 5 capsule contains 5 mg of ramipril
- * each Tryzan 10 capsule contains 10 mg of ramipril

Tryzan is also made up of:

- * pregelatinised maize starch
- * gelatin
- * titanium dioxide
- * FDA/E172 yellow iron oxide (Tryzan 1.25 and Tryzan 2.5)
- * EEC Erythrosine E127 (Tryzan 2.5)
- * carmoisine (Tryzan 5)
- * EEC Quinoline Yellow E104 (Tryzan 5)
- * brilliant scarlet 4R (Tryzan 10)
- * indigo carmine (Tryzan 10)
- * FDA/E172 Black Iron Oxide (Tryzan 10)
- * TekPrint SW-9008 Black Ink (AUST R 2328)
- * TekPrint SW-9009 Black Ink (AUST R 2343)

The capsules are gluten free.

Supplier

Tryzan is supplied by:

Alphapharm Pty Limited

(ABN 002 359 739)

Chase Building 2

Wentworth Park Road

Glebe NSW 2037

Phone: (02) 9298 3999

Medical Information

Phone: 1800 028 365

www.alphapharm.com.au

Australian registration numbers:

Tryzan 1.25: AUST R 127085

Tryzan 2.5: AUST R 127088

Tryzan 5: AUST R 127152

Tryzan 10: AUST R 127153

Tryzan Titration Pack: AUST R 127166

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