Tritace®

Consumer Medicine Information (CMI) summary

The full CMI 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 Tritace?

Tritace contains the active ingredient ramipril. Tritace 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 1. Why am I using Tritace? in the full CMI.

2. What should I know before I use Tritace?

Do not use if you have ever had an allergic reaction to Tritace 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 use Tritace? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Tritace 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 use Tritace?

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

More instructions can be found in Section 4. How do I use Tritace? in the full CMI.

5. What should I know while using Tritace?

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 Tritace.
Things you should not do	• Give Tritace to anyone else, even if they have the same condition as you. • Take Tritace 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 Tritace affects you. • As with other ACE inhibitor medicines, Tritace 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 Tritace, you may experience dizziness, drowsiness, or light-headedness.
Looking after your medicine	• Keep your Tritace tablets or capsules in the blister pack until it is time to take them. • Keep your Tritace tablets or capsules in a cool dry place where the temperature stays below 25°C.

For more information, see Section 5. What should I know while using Tritace? 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 6. Are there any side effects? in the full CMI.

Tritace®

Active ingredient(s): *ramipril*

Consumer Medicine Information (CMI)

This leaflet provides important information about using Tritace. **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 Tritace.**

Where to find information in this leaflet:

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

1. Why am I using Tritace?

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

This helps to 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.

Tritace 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.

Tritace is used to treat the following conditions:

Hypertension

Tritace 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

Tritace 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 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

Tritace 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

Tritace 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.

Tritace 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.

2. What should I know before I use Tritace?

Warnings

Do not use Tritace 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.

- 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.
- You are pregnant or intend to become pregnant.
- You are breastfeeding.

Check with your doctor if you:

- Have allergies to any other medicines or other substances such as foods, preservatives, or dyes.
- Have liver problems, low blood pressure, low white blood cell counts, high blood levels of potassium, Systemic Lupus Erythematosus (SLE), scleroderma or other autoimmune conditions.
- Have any other medical conditions such as kidney/heart problems or diabetes (note that your doctor may give you Tritace 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.

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 6. Are there any side effects?

Pregnancy and breastfeeding

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

Talk to your doctor if you are breastfeeding or intend to breastfeed. Tritace may pass into the breast milk and affect your breastfed 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 Tritace and affect how it works. These include:

- Other medicines used to treat high blood pressure.
- Other medicines 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), which are 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, hayfever, or sinus problems. A discussion with your doctor or pharmacist should occur before using these while on Tritace.

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

4. How do I use Tritace?

How much to take

Your doctor will select a dose when they prescribe Tritace for you. Some patients may need a lower starting dose. The usual dose of Tritace is:

- For high blood pressure, 2.5 to 10 mg per day.
- For heart failure, 5 to 10 mg per day.
- For kidney problems, 1.25 to 5 mg per day.
- For cardiovascular risk, 2.5 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 Tritace.

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

When to take Tritace

- Tritace should be taken at about the same time each day.
- Tritace should be swallowed whole with plenty of fluid. It does not matter if you take Tritace before or after food.
- 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.

If you forget to use Tritace

Tritace should be used 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.

- If you are not sure what to do or if you have trouble remembering when to take Tritace, ask your doctor or pharmacist for advice.

If you use too much Tritace

If you think that you have used too much Tritace, 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 Tritace?

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 light-headed, dizzy, or faint.
- Drink enough water during exercise and hot weather when you are taking Tritace, 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.
- Remind any doctor, dentist, or pharmacist you visit that you are using Tritace.
- 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 Tritace.
- Have your blood pressure checked when your doctor says, to make sure Tritace is working.

Call your doctor straight away if you:

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

Things you should not do

- Give Tritace to anyone else, even if they have the same condition as you.
- Take Tritace 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 Tritace affects you.

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

Drinking alcohol

Tell your doctor if you drink alcohol.

If you drink alcohol while taking Tritace, you may experience dizziness, drowsiness, or light-headedness.

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 and 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 programme 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 smoking.
- Weight- your doctor may suggest losing some weight to help lower your blood pressure and help lessen the amount of work your heart does. Some people may need a dietitian's help to lose weight.

Looking after your medicine

- Keep your Tritace 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.
- Keep your Tritace tablets or capsules in a cool dry place where the temperature stays 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 windowsills.

Keep it where young 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
• 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 unrelated to exercise • Unusual tiredness, weakness, or fatigue • Ringing or buzzing in the ears • Forgetfulness or confusion	**Speak to your doctor if you have any of these less serious side effects and they worry you.** **These side effects are common, and usually mild.**

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 • Itchy or raised skin rash, hives or nettle rash • 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	**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.** **These side effects are rare.**

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 • 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	**Go straight to the Emergency Department at your nearest hospital if you notice any of these very serious side effects.** **These side effects are very rare.**

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 Tritace contains

Active ingredient (main ingredient)	Ramipril

Other ingredients (inactive ingredients)	Tritace tablets also contain: Hypromellose Pre-gelatinised maize starch Microcrystalline cellulose Sodium stearyl fumarate Iron oxide yellow (2.5 mg only) Iron oxide red (5 mg only) Tritace capsules also contain: Pre-gelatinised maize starch Gelatine Indigo carmine Erythrosine Iron oxide black Titanium dioxide
Potential allergens	Tritace does not contain lactose, sucrose, gluten or tartrazine.

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

What Tritace looks like

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

Each strength appears as follows:

1.25 mg tablets: white to almost white, oblong shaped, scored tablets with 1.25 and HMN on one side, and 1.25 and a logo on the other side. AUST R 34515

2.5 mg tablets: yellowish to yellow, oblong shaped, scored tablets with 2.5 and HMR on one side, and 2.5 and a logo on the other side. AUST R 56537

5 mg tablets: pale red, oblong shaped, scored tablets with 5 and HMP on one side, and 5 and a logo on the other side. AUST R 56538

10 mg tablets: white to almost white, oblong shaped, scored tablets with HMO on one side only. AUST R 79253

10 mg capsules: blue and white, and unmarked. AUST R 75202

Tritace is available in blister packs of 30 tablets or capsules.

Who distributes Tritace

Distributed by:

sanofi-aventis australia pty ltd

International Tower 3, Level 23

300 Barangaroo Avenue

Sydney NSW 2000

Freecall: 1800 818 806

Email: medinfo.australia@sanofi.com

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