

Consumer Medicine Information (CMI) summary

The [full CMI](#) 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 Triasyn?

Triasyn contains the active ingredients ramipril and felodipine. Triasyn is used to lower high blood pressure (hypertension). For more information, see Section [1. Why am I taking Triasyn?](#) in the full CMI.

2. What should I know before I take Triasyn?

Do not take Triasyn if you have ever had an allergic reaction to ramipril or felodipine, any of the ingredients listed at the end of the CMI, or to any 'ACE inhibitor' (medicines used to treat high blood pressure and some other heart conditions).

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 Triasyn?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Triasyn 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 Triasyn?

Your doctor will tell you how many tablets you will need each day. Swallow the tablet whole with a full glass of water or other liquid at the same time each day. **Do not crush or chew the tablets.** More instructions can be found in Section [4. How do I take Triasyn?](#) in the full CMI.

5. What should I know while taking Triasyn?

Things you should do	- Remind any doctor, dentist or pharmacist you visit that you are taking Triasyn. - Drink enough water during exercise and hot weather, especially if you sweat a lot. - If you have excess vomiting or diarrhoea while taking Triasyn, tell your doctor. - Have your blood pressure checked when your doctor says. Go to your doctor regularly for checkups. - Call your doctor straight away if you feel light-headed or dizzy after taking your first dose of Triasyn or when your dose is increased. - Call your doctor straight away if you become pregnant or intend to become pregnant.
Things you should not do	- Do not give this medicine to anyone else, even if they have the same condition as you. - Do not use this medicine to treat any other complaints unless your doctor tells you to. - Do not stop taking Triasyn, 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 standing up, get up slowly.
Driving or using machines	Be careful before you drive or use any machines or tools until you know how Triasyn affects you. Triasyn may cause dizziness, light-headedness, tiredness or drowsiness in some people.
Drinking alcohol	Tell your doctor if you drink alcohol. Alcohol may affect how well Triasyn works. Dizziness or light-headedness may be worse.
Looking after your medicine	- Keep your Triasyn tablets in a cool dry place where the temperature stays below 25°C. - Keep your Triasyn tablets in the blister pack until it is time to take them.

For more information, see Section [5. What should I know while taking Triasyn?](#) in the full CMI.

6. Are there any side effects?

Very serious side effects: fainting within a few hours of taking a dose; severe dizziness and confusion with visual disturbances, speech problems; swelling of the face, lips, mouth, tongue or throat; chest pain, 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, genitals. 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.

Triasyn[®] (try-a(h)-sin)

Active ingredient(s): ramipril and felodipine (ram-(m)e-pril (and) fell-odd-ip-een)

Consumer Medicine Information (CMI)

This leaflet provides important information about taking Triasyn. **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 Triasyn.**

Where to find information in this leaflet:

1. [Why am I taking Triasyn?](#)
2. [What should I know before I take Triasyn?](#)
3. [What if I am taking other medicines?](#)
4. [How do I take Triasyn?](#)
5. [What should I know while taking Triasyn?](#)
6. [Are there any side effects?](#)
7. [Product details](#)

1. Why am I taking Triasyn?

Triasyn contains the active ingredients ramipril and felodipine. Ramipril is an angiotensin converting enzyme (ACE) inhibitor and felodipine is a calcium channel blocker.

Triasyn 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.

Triasyn 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.

2. What should I know before I take Triasyn?

Warnings

Do not take Triasyn if:

- you are allergic to ramipril or felodipine, or any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can use this medicine.
- you are allergic to any 'ACE inhibitor', medicines used to treat high blood pressure and some other heart conditions.

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

- you are taking sacubitril/valsartan therapy, medication used to treat heart failure
- 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 have unstable angina, stroke or other heart and blood flow conditions
- you are diabetic or have kidney problems and are being treated with aliskiren-containing medications (a medication also used to treat high blood pressure)
- you are pregnant or intend to become pregnant. Triasyn may affect your developing baby if you take it during pregnancy.
- you are breastfeeding. Triasyn may pass into the breast milk and there is a possibility that your baby may be affected.

Check with your doctor if you:

- are allergic to any of the ingredients listed at the end of this leaflet, or any other medicines
- are allergic to any other substances, such as foods, preservatives or dyes
- have or have had any other medical conditions, especially the following:
 - o kidney problems, or you are having dialysis
 - o liver problems
 - o heart problems
 - o low blood pressure, which you may notice as dizziness or light-headedness
 - o low white blood cell counts
 - o diabetes
 - o high levels of potassium in your blood
 - o Systemic Lupus Erythematosus (SLE), scleroderma or other autoimmune conditions.
- 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
- take any medicines for any other condition.

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.

Triasyn should not be taken during pregnancy. If you are pregnant, or intend to become pregnant, tell your doctor to discuss a change in medication and further management.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

It is not recommended to take Triasyn if you are breastfeeding.

Children and adolescents

Do not give Triasyn to a child or adolescent.

There is no experience with its use in children or adolescents under 18 years of age.

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 Triasyn and affect how it works. These include:

- other medicines used to treat high blood pressure, including those containing the active ingredient aliskiren
- sacubitril/valsartan therapy, medication used to treat heart failure
- neprilysin (NEP) inhibitors, medicines used to treat heart failure
- beta blockers
- 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 (e.g. tacrolimus), or medicines used to treat cancer
- antibiotics that contain trimethoprim
- some epilepsy medicines, sedatives, antibiotics and antifungal medicines
- medicines (including the ones bought without a prescription) for appetite control, asthma, colds, coughs, hayfever or sinus problems; do not take these medicines unless you have discussed it with your doctor or pharmacist.

These medicines may be affected by Triasyn, or may affect how well Triasyn works. You may need to use different amounts of your medicine, or take different medicines. Your doctor or pharmacist will advise you.

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

Alcohol and grapefruit juice may affect how well Triasyn works.

4. How do I use Triasyn?

How much to take

- The usual dose of Triasyn is one 2.5/2.5mg tablet or one 5.0/5.0mg tablet per day.
- Your doctor will select a dose when they prescribe Triasyn for you. This depends on your condition and whether or not you are taking any other medicines.
- Depending on your response, your doctor may adjust the dose.
- Ask your doctor if you are unsure of the correct dose for you. If you take the wrong dose, Triasyn may not work as well and your condition may not improve.
- Follow the instructions provided and take Triasyn until your doctor tells you to stop.

When to take Triasyn

Take Triasyn only when prescribed by your doctor.

Take Triasyn at about the same time each day.

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

It does not matter if you take Triasyn before, after or during a meal.

If you are not sure when to take it, ask your doctor or pharmacist.

How to take Triasyn

Swallow the tablet whole with a full glass of water or other liquid.

Do not crush or chew the tablets.

These tablets are designed so that the two active ingredients enter the bloodstream at different rates. If you crush or chew them, the active ingredients may enter your bloodstream too quickly.

How long to take Triasyn

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

Triasyn helps control your condition, but it does not cure it. Therefore, you must take it every day.

Triasyn is not addictive.

If you forget to take Triasyn

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

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

If there is still a long time to go before your next dose, take it as soon as you remember, and then go back to taking it as you would normally.

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

If you have trouble remembering when to take Triasyn, ask your doctor or pharmacist for hints.

If you take too much Triasyn

If you think that you have taken too much Triasyn, 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.

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

5. What should I know while taking Triasyn?

Things you should do

Make sure you drink enough water during exercise and hot weather when you are taking Triasyn, especially if you sweat a lot.

If you do not drink enough water while taking Triasyn, 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 Triasyn, tell your doctor.

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

If you plan to have surgery that needs a general anaesthetic, tell your doctor or dentist that you are taking Triasyn.

Your blood pressure may drop suddenly.

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

Triasyn may interfere with the results of some tests.

Have your blood pressure checked when your doctor says, to make sure Triasyn is working.

Go to your doctor regularly for a check-up.

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

Call your doctor straight away if you:

- feel light-headed or dizzy after taking your first dose of Triasyn, or when your dose is increased
- become pregnant or intend to become pregnant while taking Triasyn.

Remind any doctor, dentist or pharmacist you visit that you are using Triasyn.

Things you should not do

- Do not take more than the recommended dose unless your doctor tells you to.
- Do not give this medicine to anyone else, even if they have the same condition as you.
- Do not use this medicine to treat any other complaints unless your doctor tells you to.
- Do not stop taking Triasyn, 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 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 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.

- Limiting 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 try to find a route that is reasonably flat. Before starting any exercise, ask your doctor about the best kind of program for you.
- Watching salt intake - 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.
- Reducing 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 has to do. Some people may need a dietician's help to lose weight.

Driving or using machines

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

As with other ACE inhibitor medicines, Triasyn may cause dizziness, light-headedness, tiredness or drowsiness in some people. Make sure you know how you react to Triasyn 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, dizziness or light-headedness may be worse.

Alcohol may affect how well Triasyn works.

Looking after your medicine

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

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 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 printed on the pack. Do not take Triasyn if the packaging is torn or shows signs of tampering.

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
Alertness and sleep-related: • headache • feeling light-headed, dizzy or faint • forgetfulness or confusion • unusual tiredness or weakness, fatigue. Breathing-related: • dry cough. Infection-related: • respiratory tract infections. Stomach and gut-related: • feeling sick (nausea) or vomiting • stomach pain • diarrhoea.	Speak to your doctor if you have any of these less serious side effects and they worry you. These side effects are usually mild.

Less serious side effects	What to do
Sight, hearing, smell, taste or touch-related: • ringing or buzzing in the ears • taste disturbances or loss of taste. Skin and muscle-related: • skin sensitivity • feeling warm (flushed) • decreased physical fitness • muscle cramps. Swelling-related: • mild swelling of hands and feet • enlargement of gums.	

Serious side effects

Serious side effects	What to do
Bleeding-related: • bleeding or bruising more easily than normal. Breathing and heart-related: • shortness of breath or tightness in the chest • fast or irregular heartbeat. Infection-related: • frequent infections such as fever, severe chills, sore throat or mouth ulcers. Stomach and gut-related: • severe upper stomach pain, often with nausea and vomiting. Sight, hearing, smell, taste or touch-related: • disturbed vision • numbness or tingling in the hands or feet. Skin and muscle-related: • 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 • yellowing of the skin and/or eyes. • colour change (white, blue then red) in the fingers or toes when exposed to the cold. Other	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. Serious side effects are rare.

Serious side effects	What to do
- signs of anaemia such as tiredness, being short of breath and looking pale - passing little or no urine or more urine than is normal for you.	

Very serious side effects

Very serious side effects	What to do
Alertness and sleep-related: - fainting within a few hours of taking a dose - severe dizziness and confusion with visual disturbances and speech problems. Allergy-related: - swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing Heart-related: - chest pain. Skin-related: - 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 or genitals.	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 Triasyn contains

Active ingredient (main ingredient)	- Triasyn 2.5/2.5 mg contains 2.5 mg ramipril and 2.5 mg felodipine per tablet - Triasyn 5.0/5.0 mg contains 5 mg ramipril and 5 mg felodipine per tablet
Other ingredients (inactive ingredients)	- aluminium sodium silicate - microcrystalline cellulose - hypolose - hypromellose - iron oxide yellow - iron oxide red - lactose - macrogol 6000 - hard paraffin - PEG-40 hydrogenated castor oil - propyl gallate - sodium stearyl fumarate - pregelatinised maize starch - titanium dioxide.
Potential allergens	lactose

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

What Triasyn looks like

- Triasyn 2.5/2.5mg are apricot-coloured, circular, film-coated tablets, marked H/OD on one side and 2.5 on the other (AUST R 67184)
- Triasyn 5.0/5.0mg are reddish-brown, circular, film-coated tablets, marked H/OE on one side and 5 on the other (AUST R 67183).

Triasyn is available in blister packs of 30 tablets.

Who distributes Triasyn

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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