

Triasyn[®]

(try-a(h)-sin)

Ramipril and felodipine (ram-(m)e-pril (and) fell-odd-ip-
een)

Consumer Medicine Information (CMI)

What is in this leaflet

This leaflet answers some common questions about Triasyn.

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 this medicine 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 Triasyn is used for

Triasyn contains two types of medicine. These are an angiotensin converting enzyme (ACE) inhibitor and 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.

Ask your doctor or pharmacist if you have any questions about why it has been prescribed for you.

Triasyn is only available with a doctor's prescription.

Triasyn is not addictive.

Before you take it

When you must not take it

Do not take Triasyn if you:

- **are allergic to Triasyn or any other medicine containing ramipril or felodipine, or any of the ingredients listed at the end of this leaflet.**

Symptoms of an allergic reaction may include skin rash, itching, shortness of breath, swelling of the face, lips or tongue that may cause difficulty in swallowing or breathing, abdominal pain, muscle pain or tenderness, or joint pain.

- **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 Triasyn.

- **are taking sacubitril/valsartan therapy, medication used to treat heart failure**
- **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.**
- **have unstable angina, stroke or other heart and blood flow conditions.**
- **are diabetic or have kidney problems and are being treated with aliskiren-containing medications (a medication also used to treat high blood pressure).**
- **are pregnant or intend to become pregnant.**

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

- **are breastfeeding.**

Triasyn may pass into the breast milk and there is a possibility that your baby may be affected.

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.

Do not take Triasyn after the expiry date (EXP) printed on the pack.

If you take it after the expiry date has passed, it may not work as well.

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

Before you start to take it

Tell your doctor if you have allergies to:

- any of the ingredients listed at the end of this leaflet
- any other medicines
- any other substances, such as foods, preservatives or dyes

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

- kidney problems, or you are having dialysis
- liver problems
- heart problems
- low blood pressure, which you may notice as dizziness or light-headedness
- low white blood cell counts
- diabetes
- high levels of potassium in your blood
- 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 a general anaesthetic
- plan to become pregnant or breastfeed

If you have not told your doctor about any of the above, tell them before you take Triasyn.

Taking other medicines

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

Some medicines and Triasyn may interfere with one another. 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 it works. You may need to use different amounts of your medicine, or take different medicines. Your doctor or pharmacist will advise you.

Alcohol and grapefruit juice may affect how well Triasyn works.

Your doctor or pharmacist has more information on medicines to be careful with or to avoid while taking Triasyn.

How to take it

How much to take

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

Take Triasyn only when prescribed by your doctor.

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. Depending on your response, your doctor may adjust the dose.

Ask your doctor or pharmacist if you are unsure of the correct dose for you.

They will tell you exactly how much to take.

Follow the instructions they give you.

If you take the wrong dose, Triasyn may not work as well and your problem may not improve.

How to take it

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.

When to take it

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 long to take it

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.

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.

Do not take a double dose to make up for the dose that 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 pharmacist for hints.

If you take too much (overdose)

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

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

You may need urgent medical attention.

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

While you are taking it

Things you must do

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

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

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

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 become pregnant or intend to become pregnant while taking Triasyn, tell your doctor immediately.

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.

Things you must 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.

Be careful driving or operating machinery 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. 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 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. 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 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 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 Triasyn.

Triasyn helps most people, 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.

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

Tell your doctor if you notice any of the following and they worry you:

- feeling light-headed, dizzy or faint
- dry cough
- respiratory tract infections
- headache
- feeling sick (nausea) or vomiting
- stomach pain
- diarrhoea
- unusual tiredness or weakness, fatigue
- decreased physical fitness
- muscle cramps
- ringing or buzzing in the ears

- forgetfulness or confusion
- feeling warm (flushed)
- mild swelling of hands and feet
- skin sensitivity
- enlargement of gums
- taste disturbances or loss of taste

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

- numbness or tingling in the hands or feet
- 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. You may need medical attention. Serious side effects are rare.

If any of the following happen, stop taking Triasyn and either 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 or genitals

- chest pain

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

Other side effects not listed above may occur in some patients. Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

After taking it

If you have any questions about any aspect of your medicine, or any questions regarding the information in this leaflet, discuss them with your doctor or pharmacist.

Storage

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.

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

Heat and dampness can destroy some medicines.

Keep it 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 Triasyn, or the medicine has passed its expiry date, ask your pharmacist what to do with any that are left over.

Return any unused medicine to your pharmacist.

Product description

What it looks like

Triasyn comes in two types of tablets:

- Triasyn 2.5/2.5mg - apricot-coloured, circular, film-coated tablets, marked H/OD on one side and 2.5 on the other
- Triasyn 5.0/5.0mg - reddish-brown, circular, film-coated tablets, marked H/OE on one side and 5 on the other

Triasyn is available in blister packs of 30 tablets.

Ingredients

Active Ingredients:

- Triasyn 2.5/2.5mg - 2.5mg ramipril and 2.5mg felodipine per tablet

- Triasyn 5.0/5.0mg - 5mg ramipril and 5mg felodipine per tablet

Inactive Ingredients:

- aluminium sodium silicate
- cellulose - microcrystalline
- hyprolose
- hypromellose
- iron oxide yellow
- iron oxide red
- lactose
- macrogol 6000
- paraffin - hard
- hydrogenated castor oil
- propyl gallate
- sodium stearyl fumarate
- starch - pregelatinised maize
- titanium dioxide

Manufacturer/Sponsor

Triasyn is supplied in Australia by:

sanofi-aventis australia pty ltd

12-24 Talavera Road

Macquarie Park NSW 2113

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Australian Register Numbers

2.5/2.5mg tablets: AUST R 67184

5.0/5.0mg tablets: AUST R 67183

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