

Package leaflet: Information for the user

Triapin® 5 mg/5 mg prolonged release tablets (ramipril / felodipine)

Blind or partially sighted? Is this leaflet hard to see or read? Call +44 (0) 1302 365000 (Regulatory)

Your medicine is available using the above name but will be referred to as Triapin throughout this leaflet.

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

- What Triapin is and what it is used for
- What you need to know before you take Triapin
- How to take Triapin
- Possible side effects
- How to store Triapin
- Contents of the pack and other information

1. What Triapin is and what it is used for

Triapin contains two medicines called ramipril and felodipine.

- Ramipril belongs to a group of medicines called 'angiotensin converting enzyme inhibitors' (ACE inhibitors). It works by stopping the production of substances that raise blood pressure and makes your blood vessels relax and widen.
- Felodipine belongs to a group of medicines called 'calcium antagonists'. It makes your blood vessels relax and widen. This helps to lower your blood pressure.

Triapin is used to treat high blood pressure (hypertension). High blood pressure can mean you are more likely to have problems such as heart disease, kidney disease and stroke. This medicine lowers your blood pressure and lowers the risk of these problems.

2. What you need to know before you take Triapin

Do not take Triapin if:

- You are allergic to:
 - ramipril or any other ACE inhibitor
 - felodipine or any other calcium antagonists
 - any of the other ingredients of this medicine (listed in section 6)
- You have ever had a serious allergic reaction called "angioedema". The signs include itching, hives (urticaria), red marks on the hands, feet and throat, swelling of the throat and tongue, swelling around the eyes and lips, difficulty breathing and swallowing. Taking this medicine may increase the risk of having a more serious attack of this condition
- You have taken or are currently taking sacubitril/valsartan, a medicine used to treat a type of long-term (chronic) heart failure in adults
- You have heart problems such as heart failure, obstructions in your heart, angina which is unstable, a heart condition known as atrioventricular block II or III, a heart attack (acute myocardial infarction) or a stroke (disturbance of the blood circulation in the brain)
- You have a severe kidney problem
- You are having dialysis
- You have a severe liver problem

- You are pregnant, trying to get pregnant or breast-feeding (see 'Pregnancy and breast-feeding' below)
- You have diabetes or impaired kidney function and you are treated with a blood pressure lowering medicine containing aliskiren.

Do not take this medicine if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking Triapin.

Warnings and precautions

Talk to your doctor or pharmacist before taking Triapin if:

- You have kidney problems, diabetes mellitus or are taking medicines which increase potassium. Your doctor may carry out regular blood tests, particularly for checking the levels of potassium in your blood
- You are taking medicines or have conditions which may decrease sodium levels in your blood. Your doctor may carry out regular blood tests, particularly for checking the levels of sodium in your blood especially if you are elderly
- You are taking medicines that may increase the risk of angioedema, a serious allergic reaction, such as mTOR inhibitors (e.g. temsirolimus, everolimus, sirolimus), vildagliptin, neprilysin (NEP) inhibitors (such as racecadotril) or sacubitril/valsartan. For sacubitril/valsartan, see section 2 'Do not take Triapin if'
- You have kidney artery problems
- You have narrowing of the main blood vessel leading from the heart (aortic stenosis) or heart muscle disease (hypertrophic cardiomyopathy)
- You have any other heart problem
- You have systemic lupus erythematosus or scleroderma
- You suffer from liver problems
- You are going to have an anaesthetic or surgery
- You are taking medicines which lower the number of certain blood cells
- You are black because the medicine may have less effect on your blood pressure and more side effects
- You are going to have treatment to lower the effect of an allergy to bee or wasp stings (desensitization)
- You are having treatment where your blood is treated outside the body, such as "low-density lipoprotein apheresis"
- You have swelling in your gums which may be a sign of gingivitis or periodontitis. Careful dental hygiene may be necessary to avoid additional gum problems, such as a condition which increases the size of your gums
- You are taking any of the following medicines used to treat high blood pressure:
 - an angiotensin II receptor blocker (ARBs) (also known as sartans - for example valsartan, telmisartan, irbesartan), in particular if you have diabetes-related kidney problems
 - aliskiren

Your doctor may check your kidney function, blood pressure, and the amount of electrolytes (e.g. potassium) in your blood at regular intervals.

See also information under the heading "Do not take Triapin if".

Other medicines and Triapin

Tell your doctor or pharmacist if you are using, have recently taken or might take any other medicines. This includes medicines obtained without a prescription, including herbal medicines. This is because Triapin can affect the way some other medicines work. Also some medicines can affect the way Triapin work.

In particular, tell your doctor if you are taking or being treated with any of the following:

- Sacubitril/valsartan – used for treating a type of long-term (chronic) heart failure in adults (see section 2 'Do not take Triapin if')
- Medicines for lowering high blood pressure (antihypertensives), including those containing aliskiren, and other medicines that lower blood pressure (nitrates, antipsychotics, narcotics and anaesthetics)
- Medicines to treat HIV infection
- Procainamide – used for treating heart rhythm disorders
- Water tablets (diuretics) which can cause high blood potassium such as amiloride, spironolactone, triamterene
- Heparin – used for thinning the blood
- Lithium preparations - used to treat mania, depression and manic-depressive illness
- Phenytoin, carbamazepine and barbiturates. These medicines are usually used to treat epilepsy, fits and convulsions. Barbiturates are also used for sleeping problems
- Theophylline – used for treating asthma

- Sympathomimetics such as adrenaline, noradrenaline or ephedrine (medicines which act on the heart and blood vessels)
- Erythromycin, itraconazole, ketoconazole – used for treating infections
- Rifampicin – used for treatment of tuberculosis
- Allopurinol – used for treating gout
- Non-steroidal anti-inflammatory drugs (NSAIDs) – used to relieve pain and inflammation
- Immunosuppressants – used in rheumatoid arthritis or after organ transplants
- Tacrolimus which is a medicine given to prevent the body from rejecting a transplanted organ, such as a kidney or liver
- Sirolimus, everolimus (for prevention of graft rejection)
- Racecadotril - used against diarrhoea
- Temsirolimus (for cancer)
- Cytostatics – used to treat cancer
- Insulin, glibenclamide, metformin, vildagliptin and other medicines used for diabetes mellitus
- Glucocorticoids ('steroids')
- Potassium salts
- Trimethoprim alone or in combination with sulfamethoxazole used for infections
- St John's Wort

Your doctor may need to change your dose and/or to take other precautions:

- If you are taking an angiotensin II receptor blocker (ARB) or aliskiren (see also information under the headings "Do not take Triapin if" and "Warnings and precautions").

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before taking Triapin.

Triapin with food and drink

- Taking your tablet with alcohol may increase the effect of your medicine
- Taking this medicine with grapefruit juice is not recommended
- Increasing the amount of salt in your diet may lower the effect of this medicine
- Take the tablets on an empty stomach or after eating a light meal

Pregnancy and breast-feeding

Do not take Triapin if:

- You are pregnant, might become pregnant or think you may be pregnant. This is because the medicine could harm your baby
- You are breast-feeding or planning to breast-feed. This is because small amounts may pass into the mother's milk

If you suspect you have become pregnant while taking Triapin, you should talk to your doctor immediately.

Driving and using machines

You may feel dizzy or light-headed after taking this medicine. If this happens, do not drive or use any tools or machines.

Triapin contain lactose and polyoxyl 40 hydrogenated castor oil

This medicine contains lactose, a type of sugar. If you have been told by your doctor that you cannot tolerate some sugars, talk to your doctor before taking this medicine. This medicine contains polyoxyl 40 hydrogenated castor oil. It may cause stomach upset or diarrhoea.

3. How to take Triapin

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure. Triapin is for adults only. Do not give them to children.

Taking this medicine

- Take this medicine by mouth.
- Take the tablets on an empty stomach or after eating a light meal.
- Swallow the tablets whole with half a glass of water or other drink. Do not break, crush or chew the tablets.
- Do not take your tablets with grapefruit juice or alcohol.

How much to take

- The usual dose is 1 Triapin 2.5mg/2.5mg prolonged release tablet or 1 Triapin 5mg/5mg prolonged release tablet taken once a day
- Your doctor may start you on Triapin 2.5mg/2.5mg prolonged release tablets and then change you to Triapin 5mg/5mg prolonged release tablets to increase your dose
- The maximum dose is either 2 Triapin 2.5mg/2.5mg prolonged release tablets once a day or 1 Triapin 5mg/5mg prolonged release tablet once a day
- If you are already taking diuretics (water tablets), your doctor may stop or reduce the amount of the diuretic you take before beginning treatment with Triapin.

Use in children

Do not give Triapin to children.

If you take more Triapin than you should

If you take more Triapin than you should, tell a doctor or go to the nearest hospital casualty department straight away. Take the medicine pack with you. This is so the doctor knows what you have taken. You may feel dizzy and light-headed because your blood pressure is too low.

If you forget to take Triapin

If you forget to take a dose and remember on the same day:

- Take it as soon as you remember
- On the next day, take your usual dose of Triapin

If you forget to take a dose and remember this the next day:

- Take only your usual dose of Triapin
- Do not take a double dose to make up for a forgotten dose

If you stop taking Triapin

Keep taking treatment until your doctor tells you to stop.

Do not stop taking this medicine just because you feel better.

If you stop, your blood pressure may rise again.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Stop taking Triapin and see a doctor straight away, if you notice any of the following serious side effects – you may need urgent medical treatment:

- Swelling of the face, lips or throat which make it difficult to swallow or breathe, as well as itching and rashes. These could be signs of a severe allergic reaction to Triapin
- Severe skin reactions including rash, ulcers in your mouth, worsening of a pre-existing skin disease, reddening, blistering or detachment of skin (such as Stevens-Johnson syndrome, toxic epidermal necrolysis or erythema multiforme).

Tell your doctor immediately if you experience:

- Faster heart rate, uneven or forceful heartbeat (palpitations), chest pain, tightness in your chest or more serious problems including heart attack and stroke
- Shortness of breath or a cough. These could be signs of lung problems
- Bruising more easily, bleeding for longer than normal, any sign of bleeding (e.g. bleeding from the gums), purple spots, blotching on the skin or getting infections more easily than usual, sore throat and fever, feeling tired, faint, dizzy or having pale skin. These can be signs of blood or bone marrow problems
- Severe stomach pain which may reach through to your back. This could be a sign of pancreatitis (inflammation of the pancreas)
- Fever, chills, tiredness, loss of appetite, stomach pain, feeling sick, yellowing of your skin or eyes (jaundice). These can be signs of liver problems such as hepatitis (inflammation of the liver) or liver damage.

Other side effects include:

Please tell your doctor if any of the following gets serious or lasts longer than a few days.

Very Common (may affect more than 1 in 10 people)

- Swollen arms and legs. This may be a sign of your body holding onto more water than usual

Common (may affect up to 1 in 10 people)

- Headache or feeling tired
- Feeling dizzy. This is more likely to happen when you start taking Triapin or start taking a higher dose
- Fainting, hypotension (abnormally low blood pressure), especially when you stand or sit up quickly
- Flushing
- Dry tickly cough, inflammation of your sinuses (sinusitis) or bronchitis, shortness of breath
- Stomach or gut pain, diarrhoea, indigestion, feeling or being sick
- Skin rash with or without raised area
- Chest pain
- Cramps or pain in your muscles
- Blood tests showing more potassium than usual in your blood.

Uncommon (may affect up to 1 in 100 people)

- Balance problems (vertigo)
- Itching and unusual skin sensations such as numbness, tingling, pricking, burning or creeping on your skin (paraesthesia)
- Loss or change in the way things taste
- Sleep problems
- Feeling depressed, anxious, more nervous than usual or restless
- Blocked nose, difficulty breathing or worsening of asthma
- A swelling in your gut called “intestinal angioedema” presenting with symptoms like abdominal pain, vomiting and diarrhoea
- Heartburn, constipation or dry mouth
- Passing more water (urine) than usual over the day
- Sweating more than usual
- Loss or decrease of appetite (anorexia)
- Increased or irregular heartbeats
- Blurred vision
- Pain in your joints
- Fever
- Sexual inability in men, reduced sexual desire in men or women
- An increased number of certain white blood cells (eosinophilia) found during a blood test
- Blood tests showing changes in the way your liver, pancreas or kidneys are working.

Rare (may affect up to 1 in 1,000 people)

- Feeling shaky or confused
- Red and swollen tongue
- Severe flaking or peeling of the skin, itchy, lumpy rash
- Nail problem (e.g. loosening or separation of a nail from its bed)
- Skin rash or bruising
- Blotches on your skin and cold extremities
- Red, itchy, swollen or watery eyes
- Disturbed hearing and ringing in your ears
- Feeling weak
- Blood tests showing a decrease in the number of red blood cells, white blood cells or platelets or in the amount of haemoglobin
- Reduced sexual function in men or women.

Very rare (may affect up to 1 in 10,000 people)

- Being more sensitive to the sun than usual
- Slight swelling of your gums or bleeding gums
- Blood tests showing more sugar than usual in your blood.

Other side effects reported:

Please tell your doctor if any of the following gets serious or lasts longer than a few days.

- Difficulty concentrating
- Swollen mouth
- Blood tests showing too few blood cells in your blood
- Blood tests showing less sodium than usual in your blood
- Concentrated urine (dark in colour), feel or are sick, have muscle cramps, confusion and fits which may be due to inappropriate ADH (anti-diuretic hormone) secretion. If you have these symptoms contact your doctor as soon as possible
- Fingers and toes changing colour when you are cold and then tingling or feeling painful when you warm up (Raynaud’s phenomenon)
- Breast enlargement in men
- Slowed or impaired reactions
- Burning sensation
- Change in the way things smell
- Hair loss.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly (see details below). By reporting side effects, you can help provide more information on the safety of this medicine.

HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2.

Tel: +353 1 6764971

Fax: +353 1 6762517

Website: www.hpra.ie

e-mail: medsafety@hpra.ie

5. How to store Triapin

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and blister strips after EXP. The expiry date refers to the last day of that month.

Do not store above 25°C.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Triapin contains

The active substances are ramipril and felodipine.

Each tablet contains 5 mg of ramipril and 5 mg of felodipine.

The other ingredients are: microcrystalline cellulose, hypromellose, hypromellose, iron oxide E172, lactose anhydrous, macrogol, polyoxyl 40 hydrogenated castor oil, maize starch, paraffin, propyl gallate, sodium silicate of aluminium, sodium stearyl fumarate and titanium dioxide E171.

What Triapin looks like and contents of the pack

Triapin are circular, reddish-brown coloured, biconvex and engraved H/OE on one side and marked 5 on the other side. Pack size: 28 prolonged-release tablets.

Manufacturer

Manufactured by:

Chinoi Private Co. Ltd – Veresegyhasz Hungary.

Procured from within the EU and repackaged by:

Doncaster Pharmaceuticals Group Ltd., Kirk Sandall, Doncaster, DN3 1QR, UK.

PPA holder: Imbat Ltd., Unit L2, North Ring Business Park, Santry, Dublin 9.

Distributed by: Eurodrug Ltd., Unit L2, North Ring Business Park, Santry, Dublin 9.

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This medicinal product is authorised in the Member States of the EEA under the following names:

Ireland, Italy, Portugal, Spain, United Kingdom: Triapin

Italy, Portugal: Triapin Mite

Belgium, Luxembourg: Tazko

Greece: Triacor

Germany: Delmuno

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