

PACKAGE LEAFLET: INFORMATION FOR THE USER

Trialix® 5mg/6mg Tablets

Ramipril 5mg  
Piretanide 6mg



Is this leaflet hard to see or read?  
Phone 01 403 5600 for help

Read all of this leaflet carefully before you start using 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.

What is in this leaflet:

1. What Trialix Tablets are and what they are used for
2. What you need to know before you take Trialix Tablets
3. How to take Trialix Tablets
4. Possible side effects
5. How to store Trialix Tablets
6. Contents of the pack and other information

1. What Trialix Tablets are and what they are used for

What Trialix Tablets are

The name of your medicine is Trialix 5mg/6mg Tablets (called Trialix Tablets throughout this leaflet). Trialix Tablets contain two medicines called ramipril and piretanide.

Trialix is a combination product with one ingredient belonging to a group of medicines called ACE (Angiotensin Converting Enzyme) Inhibitors which act on the heart and blood vessels. It also contains a diuretic which helps you to pass more water (urine) than you usually do.

What Trialix Tablets are used for

Trialix Tablets can be used:

- To continue treatment of high blood pressure (hypertension) in those patients who are insufficiently controlled with monotherapy (treatment with ramipril or piretanide alone).

How Trialix Tablets work

Trialix Tablets work by:

- Decreasing your body's production of substances that could raise your blood pressure.
- Making your blood vessels relax and widen
- Making it easier for your heart to pump blood around your body
- Helping you to pass more water (urine) than you usually do

2. What you need to know before you take Trialix Tablets

Do not take Trialix Tablets:

- If you are allergic (hypersensitive) to ramipril, piretanide, any other ACE inhibitor medicine or any of the other ingredients of Trialix Tablets (listed in Section 6 below). Signs of an allergic reaction include: a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue
- If you are allergic to sulphonamides.
- If 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.
- If you have ever had a serious allergic reaction called 'intestinal angioedema'. The signs include abdominal pain (with or without nausea or vomiting).
- If you have taken or are currently taking sacubitril/valsartan, a medicine used to treat a type of long-term (chronic) heart failure in adults.
- If you have heart problems such as heart failure
- If you have hypertension and are taking medicine, containing aliskiren, to treat it.
- If you are having dialysis or any other type of blood filtration. Depending on the machine that is used, Trialix Tablets may not be suitable for you.
- If you have diabetes or impaired kidney function and you are treated with a blood pressure lowering medicine containing aliskiren.
- If you have kidney problems where the blood supply to your kidney is reduced (renal artery stenosis).
- If you have severe kidney problems. Including history of kidney transplantation.
- If you have severe liver problems.
- If you are not passing any water.
- If you have too little sodium, potassium, calcium, uric acid, and glucose in your blood (shown in blood tests).
- If you have a low white blood cell count. It is recommended that the white blood cell count be monitored to permit detection of a possible leucopenia.
- If your blood pressure is abnormally low or unstable. Your doctor will need to make this assessment.
- If you are pregnant or breast-feeding (see "Pregnancy and breast-feeding" section below).
- Trialix Tablets should never be given to children.
- Trialix Tablets does not represent treatment of choice for primary hyperaldosteronism.

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

Warnings and Precautions

Take special care with Trialix Tablets

Talk to your doctor or pharmacist before taking Trialix Tablets if:

- You are elderly
- You have heart, liver or kidney problems
- If you have ever had severe and malignant hypertension. The initial phase of treatment requires close medical supervision.
- You have diabetes
- You have low blood pressure or feel dizzy when you stand up

- If 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, etc.), 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 information under the heading 'Do not take Trialix Tablets'.

- You have gout
- You feel dizzy or dehydrated. This can happen if you have lost a lot of body salts or fluids (through being sick (vomiting), having diarrhoea, sweating more than usual, being on a low salt diet, passing water very often or having had dialysis. It can also happen if you are having trouble drinking or eating
- If you have been pre-treated with diuretics (drugs to increase the rate of urination)
- You are going to receive an anaesthetic. This may be given for an operation or any dental work. You may need to stop your Trialix Tablets treatment one day beforehand; ask your doctor for advice
- You have high levels of potassium in your blood (shown in blood test results)
- You have collagen vascular disease such as scleroderma or systemic lupus erythematosus
- You must tell your doctor if you think that you are (or might become) pregnant. Trialix Tablets should not be used during pregnancy.

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

Other medicines and Trialix Tablets

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

This includes medicines you buy without a prescription, including herbal medicines.

This is because Trialix Tablets can affect the way some other medicines work. Also, some medicines can affect the way Trialix Tablets work. Your doctor may need to change your dose and/or take other precautions. If you are taking an angiotensin II receptor blocker (ARB) or aliskiren see also information under the headings 'Do not take Trialix Tablets' and 'Warnings and Precautions'.

In particular, tell your doctor if you are taking 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 Trialix Tablets'). There is an increased risk of angioedema in patients taking ACE inhibitors with sacubitril/valsartan.
- Medicines used to relieve pain and inflammation (e.g. Non-Steroidal Anti-Inflammatory Drugs (NSAIDs)) such as indomethacin, aspirin.
- Medicines used for the treatment of high and low blood pressure, shock, cardiac failure, asthma or allergies. Your doctor will need to check your blood pressure.
- Medicines containing aliskiren used to treat hypertension.
- Medicines which suppress the immune response such as corticoids, cytostatics & antimetabolites.
- Medicines which can increase the amount of potassium in your blood such as spironolactone, potassium salts and heparin (for thinning blood).
- Medicines used to lower the uric acid in your blood such as Allopurinol.
- Medicines used as a general anaesthetic for relaxing your muscles during surgery.
- If you are going to have treatment to reduce your allergy to bee or wasp stings (desensitisation).
- Medicines for diabetes. These may not work as well when you are using Trialix Tablets.
- Vildagliptin - a medicine for diabetes. There has been an increased incidence of angioedema in patients taking Vildagliptin and ACE inhibitors.
- Lithium – used for mental illnesses. To help stop side effects your doctor may need to change the dose of your lithium and check the amount of lithium in your blood.
- Medicines used for heart problems including digitalis preparations. Your doctor may need to change the dose of your medicine.
- Medicines used for depression.
- Medicines used for sleeping disorders.
- mTOR Inhibitors e.g. temsirolimus, a medicine used to treat certain types of cancer.
- Trimethoprim and co-trimoxazole (for infections)
- Everolimus (for prevention of graft rejection)
- Corticosteroids – used for inflammation.
- Carbenoxolene – used for ulcers of the foodpipe (gullet)
- Liquorice – often used in cough medicines if taken in large amounts.
- Probenecid.
- Procainamide (for heart rhythm problems).
- Nephrihsyn (NEP) inhibitors e.g. racecadotril (a medicine used to treat diarrhoea).There is an increased risk of angioedema in patients taking ACE inhibitors and NEP inhibitors.
- Medicines for infections (e.g. aminoglycoside antibiotics).
- Medicines used for constipation (laxatives) if used for a long time.
- Potassium salts, potassium retaining diuretics (e.g. spironolactone, amiloride, triamterene) or other medicines which may increase kalaemia.
- Glucocorticoids ('steroids')
- Diuretics (water tablets) such as amiloride.

Trialix Tablets with food and alcohol

Drinking alcohol with Trialix Tablets may make you feel dizzy or light headed. If you are concerned about how much you can drink while taking Trialix Tablets discuss this with your doctor as taking medicines used to reduce blood pressure and alcohol can have additive effects. Trialix Tablets may be taken with or without food. You should avoid too much salt in your diet.

Pregnancy, breast-feeding and fertility

Do not take Trialix Tablets if you are pregnant. Talk to your doctor before taking this medicine if you are pregnant, might become pregnant, or think you might be pregnant.

Do not breast-feed if you are taking Trialix Tablets. This is because small amounts may pass into the mother's milk. If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Driving and using machines

You may feel dizzy or unwell after taking Trialix Tablets. If this happens, do not drive or use any tools or machines.

3. How to take Trialix Tablets

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Taking this medicine

- Take this medicine by mouth at the same time of the day each day
- Swallow your tablets with a glass of water
- Do not crush or chew the tablets

How much to take

Adults:

- The usual dose is one tablet daily to be taken in the morning.

Elderly and renal impaired:

- The usual dose is half a tablet daily.

If you take more Trialix Tablets than you should

If you take more Trialix Tablets than you should contact your doctor immediately or consult with your nearest hospital casualty department. Take the medicine pack with you this is so the doctor knows what you have taken.

If you forget to take Trialix Tablets

- If you miss a dose take your normal dose when it is next due.
- Do not take a double dose to make up for a forgotten tablet.

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

4. Possible side effects

Like all medicines, Trialix Tablets can cause side effects, although not everybody gets them.

Stop taking Trialix Tablets 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 makes it difficult to swallow or breathe, as well as itching and rashes. This could be a sign of a severe allergic reaction to Trialix Tablets.
- 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 multiform).
- 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 or stroke.
  - Shortness of breath or a cough. These could be signs of lung problems.
  - Bruising more easily, bleeding for longer than normal, any signs 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 signs 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.
  - Increased thirst, headache, feeling dizzy or light-headed, fainting, confusion, muscle or joint pains or weakness, cramps or spasms, stomach upsets or uneven heartbeats. These could be signs of dehydration or changes in your normal body chemicals. Severe dehydration can lead to blood clots (thrombosis) or 'gout'.
  - Problems hearing or ringing in the ears (tinnitus). This especially affects people who already have problems with their kidneys

Other side effects include:

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

Common (affects less than 1 in 10 people)

- Headache or feeling tired
- Feeling dizzy. This is more likely to happen when you start taking Trialix Tablets or start taking a higher dose
- Fainting, hypotension (abnormally low blood pressure), especially when you stand or sit up quickly
- 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 (affects less than 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
- Swollen arms and legs. This may be a sign of your body holding onto more water than usual
- Flushing
- Visual disturbance including 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 (affects less than 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.

Very rare (affects less than 1 in 10,000 people)

- Being more sensitive to the sun than usual.

Not Known: (frequency cannot be estimated from available data)

- 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.

Other side effects reported:

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

- Difficulty concentrating
  - Difficulty in passing water (urine)
  - Development of fluid depletion
  - Muscle weakness
  - Involuntary contraction of your muscles (tetany)
  - Swollen mouth
  - An increase in total cholesterol level and triglycerides (a type of fat) in your blood
  - An increase of uric acid in your blood
  - Blood tests showing too few blood cells in your blood
  - Blood tests showing less sodium or potassium than usual in your blood
  - An increase in the proportion of red blood cells relative to the plasma (haemoconcentration)
  - An increase of calcium and magnesium excretion
  - 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
  - Formation of blood clots (thrombosis)
  - Development or worsening of a metabolic alkalosis (a pH imbalance that occurs when the body accumulates too much of an alkaline substance e.g. bicarbonate)
  - Slowed or impaired reactions
  - Burning sensation
  - Change in the way things smell
  - Increased thirst.
  - Hair loss
  - If you have diabetes you may be less able to control the levels of glucose in your blood.
  - Water retention, difficulty in passing water and reduced levels of sodium in your blood may be a sign that excess hormones are being secreted.
- 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 via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2.  
Tel: +353 1 6764971  
Fax: +353 1 6762517  
Website: [www.hpra.ie](http://www.hpra.ie)  
E-mail: [medsafety@hpra.ie](mailto:medsafety@hpra.ie)  
By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Trialix Tablets

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; after EXP. The expiry date refers to the last day of that month. Do not store above 25°C. Store in the original package. 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 Trialix Tablets contain

Trialix 5mg/6mg Tablets contain two active ingredients: ramipril and piretanide. Each tablet contains 5mg ramipril and 6mg piretanide. The other ingredients are hypromellose, pregelatinised starch, microcrystalline cellulose and magnesium stearate.

What Trialix Tablets looks like and contents of the pack

Trialix 5mg/6mg Tablets are yellowish/white oblong tablets with a scoreline.

Trialix 5mg/6mg Tablets are available in packs of 28 tablets.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

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This leaflet does not contain all the information about your medicine. If you have any questions or are not sure about anything, ask your doctor or pharmacist.

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