

Triltec® Plus

5 mg/12.5 mg, 5 mg/25 mg and 10 mg/12.5 mg tablets
Ramipril/Hydrochlorothiazide

USE IN PREGNANCY

When used in pregnancy during the second and third trimesters, drugs that act directly on the renin-angiotensin system can cause injury and even death to the developing fetus.

When pregnancy is detected, Triltec® Plus should be discontinued as soon as possible. See **Pregnancy and breast-feeding**.

Read all of this leaflet carefully before you start taking this medicine.

- 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. Do not pass it on to others. It may harm them even if their symptoms are the same as yours.
- If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet

1. What Triltec® Plus is and what it is used for
2. Before you take Triltec® Plus
3. How to take Triltec® Plus
4. Possible side effects
5. How to store Triltec® Plus
6. Further information

1. WHAT Triltec® Plus IS AND WHAT IT IS USED FOR

Triltec® Plus is a combination of two medicines called ramipril and hydrochlorothiazide.

Ramipril belongs to a group of medicines called “ACE inhibitors” (Angiotensin Converting Enzyme Inhibitors). It works by:

- Decreasing your body’s production of substances that raise your blood pressure
- Making your blood vessels relax and widen
- Making it easier for your heart to pump blood around your body

Hydrochlorothiazide belongs to a group of medicines called “thiazide diuretics” or water tablets. It works by increasing the amount of water (urine) you produce. This lowers your blood pressure.

Triltec® Plus is used to treat high blood pressure.

2. BEFORE YOU TAKE Triltec® Plus

Do not take Triltec® Plus:

- If you are allergic (hypersensitive) to ramipril, hydrochlorothiazide or any of the other ingredients of Triltec® Plus (see section 6).
- If you are allergic (hypersensitive) to medicines similar to Triltec® Plus (other ACE inhibitors or sulphonamide derived medicines).
- Signs of an allergic reaction may include a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue.
- 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 are having dialysis or any other type of blood filtration. Depending on the machine that is used, Triltec® Plus may not be suitable for you.
- If you have severe liver problems.
- If you have abnormal amounts of salts (calcium, potassium, sodium) in your blood.
- If you have kidney problems where the blood supply to your kidney is reduced (renal artery stenosis) or if you do not produce urine.
- During the second and third trimesters of pregnancy (see section below on “Pregnancy and breast-feeding”).
- If you are breast-feeding (see section below on “Pregnancy and breast-feeding”).

Do not take Triltec® Plus if any of the above apply to you. If you are not sure, talk to your doctor before taking Triltec® Plus.

Take special care with Triltec® Plus

Check with your doctor or pharmacist before taking your medicine:

- If you have heart, liver or kidney problems.
- If you have lost a lot of body salts or fluids (vomiting, diarrhoea, sweating more than usual, being on a low salt diet, taking diuretics (water tablets) for a long time or having had dialysis).
- If you are going to have treatment to reduce your allergy to bee or wasp stings (desensitization).

- If you are going to receive an anaesthetic. This may be given for an operation or any dental work. You may need to stop your Triltec® Plus treatment one day beforehand; ask your doctor for advice.
- If you have high amounts of potassium in your blood (shown in blood test results).
- If you have a 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. Triltec® Plus is not recommended in the second and third trimesters of pregnancy and may cause serious harm to your baby after 3 months of pregnancy (see section below on “Pregnancy and breast-feeding”).

Children: Triltec® Plus is not recommended for children and young people under the age of 18 years. This is because the drug has never been used in these age groups.

If any of the above apply to you (or you are not sure), talk to your doctor before taking Triltec® Plus.

Taking Triltec® Plus with other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription (including herbal medicines). This is because Triltec® Plus can affect the way some other medicines work. Also some medicines can affect the way Triltec® Plus works.

Please tell your doctor if you are taking any of the following medicines. They can make Triltec® Plus work less efficiently:

- Medicines used to relieve pain and inflammation (e.g. Non-Steroidal Anti-Inflammatory Drugs (NSAIDs) such as ibuprofen or indomethacin and aspirin)
- Medicines used for the treatment of low blood pressure, shock, cardiac failure, asthma or allergies such as ephedrine, noradrenaline or adrenaline. Your doctor will need to check your blood pressure.

Please tell your doctor if you are taking any of the following medicines. They can increase the chance of getting side effects if you take them with Triltec® Plus:

- Medicines used to relieve pain and inflammation (e.g. Non-Steroidal Anti-Inflammatory Drugs (NSAIDs) such as ibuprofen or indomethacin and aspirin)
- Medicines which can lower the amount of potassium in your blood. These include medicines for constipation, diuretics (water tablets), amphotericin B (used for fungal infections) and ACTH (used to test if your adrenal glands are working properly).
- Medicines for cancer (chemotherapy)
- Medicines for heart problems, including problems with your heartbeats
- Medicines to stop the rejection of organs after a transplant such as ciclosporin
- Diuretics (water tablets) such as furosemide
- Medicines which can increase the amount of potassium in your blood such as spironolactone, triamterene, amiloride, potassium salts, and heparin (for thinning blood)
- Steroid medicines for inflammation such as prednisolone
- Calcium supplements
- Allopurinol (used to lower the uric acid in your blood)
- Procainamide (for heart rhythm problems)
- Colestyramine (for reducing fat amounts in your blood)
- Carbamazepine (for epilepsy)
- Drugs of the same family known as renin-angiotensin system inhibitors (RAS inhibitors) including angiotensin converting enzyme inhibitors, angiotensin receptor blockers and aliskiren, because it is associated with risk of hypotension, syncope, hyperkalemia and changes in renal function compared to monotherapy.
- Your blood pressure, renal function and electrolytes should closely be monitored if you are on Triltec® Plus and other agents that affect the RAS.

If you suffer from diabetes or renal impairment, avoid using Triltec® Plus concomitantly with aliskiren.

Please tell your doctor if you are taking any of the following medicines. They may be affected by Triltec® Plus:

- Medicines for diabetes such as oral glucose lowering medicines and insulin. Triltec® Plus may lower your blood sugar amounts. Check your blood sugar amounts closely while taking Triltec® Plus.
- Lithium (for mental health problems). Triltec® Plus may increase the amount of lithium in your blood. Your lithium amount will need to be closely checked by your doctor.
- Muscle relaxants
- Quinine (for malaria)
- Medicines that contain iodine, these may be used when you are having a scan or X-ray at the hospital
- Penicillin (for infections)
- Medicines to thin the blood that you take by mouth (oral anticoagulants) such as acenocoumarol

If any of the above apply to you (or you are not sure), talk to your doctor before taking Triltec® Plus.

Tests

Check with your doctor or pharmacist before taking your medicine:

- If you are being tested for parathyroid function, Triltec® Plus might affect the results of the test.
- If you are athletic and being tested for antidoping, Triltec® Plus might give you a positive result.

Taking Triltec® Plus with food and alcohol

- Drinking alcohol with Triltec® Plus may make you feel dizzy or light-headed. If you are concerned about how much you can drink while you are taking Triltec® Plus, discuss this with your doctor as medicines used to reduce blood pressure and alcohol can have additive effects.
- Triltec® Plus may be taken with or without food.

Pregnancy and breast-feeding

You must tell your doctor if you think that you are (or might become) pregnant. You should not take Triltec® Plus in the second and third trimesters of pregnancy, as its use can cause injury and even death to the developing fetus.

If you become pregnant while on Triltec® Plus, tell your doctor immediately. When pregnancy is detected, Triltec® Plus should be discontinued immediately. A switch to a suitable alternative treatment should be carried out in advance of a planned pregnancy.

You should not take Triltec® Plus if you are breast-feeding. Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines

You may feel dizzy, while taking Triltec® Plus. This is more likely to happen when you start taking Triltec® Plus or start taking a higher dose. If this happens, do not drive or use any tools or machines.

3. HOW TO TAKE Triltec® Plus

Always take Triltec® Plus exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Taking this medicine

- Take this medicine by mouth at the same time of day each day, usually in the morning.
- Swallow the tablets with liquid.
- Do not crush or chew the tablets.

How much to take

Your doctor will determine the starting dose taking into consideration previous blood pressure treatment.

If you take more Triltec® Plus than you should

Tell a doctor or go to the nearest hospital casualty department straight away. Do not drive to the hospital, get somebody else to take you or call for an ambulance. Take the medicine pack with you, so the doctor knows what you have taken.

If you forget to take Triltec® Plus

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 product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Triltec® Plus can cause side effects, although not everybody gets them.

Stop taking Triltec® Plus 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. This could be a sign of a severe allergic reaction to Triltec® Plus.
- 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 and stroke
- Shortness of breath, cough, fever lasting 2 to 3 days and feeling less hungry. These could be signs of lung problems including inflammation.
- 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 hepati-

tis (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.**
- Common** (affects less than 1 in 10 people)
 - Headache, feeling week or tired
 - Feeling dizzy. This is more likely to happen when you start taking Triltec® Plus or start taking a higher dose
 - Dry tickly cough or bronchitis
 - Blood test showing a higher amount of sugar than usual in your blood. If you have diabetes, this may make your diabetes worse
 - Blood test showing a higher amount of uric acid or more fat than usual in your blood
 - Painful, red, and swollen joints

Uncommon

- (affects less than 1 in 100 people)
 - Skin rash with or without raised area
 - Flushing, fainting, hypotension (abnormally low blood pressure), especially when you stand or sit up quickly
 - 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 or shaky than usual
 - Blocked nose, inflammation of your sinuses (sinusitis), shortness of breath
 - Inflammation of the gums (gingivitis), swollen mouth
 - Red, itchy, swollen or watery eyes
 - Ringing in your ears
 - Blurred vision
 - Hair loss
 - Chest pain
 - Pain in your muscles
 - Constipation, stomach or gut pain
 - Indigestion or feeling sick
 - Passing more water (urine) than usual over the day
 - Sweating more than usual or feeling thirsty
 - Loss or decrease of appetite (anorexia), feeling less hungry
 - Increased or irregular heartbeat
 - Swollen arms and legs. This may be a sign of your body holding onto more water than usual
 - Fever
 - Sexual inability in men
 - Blood tests showing a decrease in the number of red blood cells, white blood cells or platelets or in the amount of haemoglobin
 - Blood tests showing changes in the way your liver, pancreas or kidneys are working
 - Blood tests showing less potassium than usual in your blood

Very rare

- (affects less than 1 in 10,000 people)
 - Vomiting, diarrhoea or heartburn
 - Red swollen tongue or dry mouth
 - Blood tests showing more potassium 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, feeling restless or confused
 - Fingers and toes changing colour when cold and then tingling or painful when you warm up. This could be Raynaud’s phenomenon.
 - Breast enlargement in men
 - Blood clots
 - Disturbed hearing
 - Your eyes watering less than usual
 - Objects looking yellow
 - Dehydration
 - Swelling, pain and redness in your cheek (inflammation of a salivary gland)
 - A swelling in your gut called “intestinal angioedema” presenting with symptoms like abdominal pain, vomiting and diarrhoea
 - Being more sensitive to the sun than usual
 - Severe flaking or peeling of the skin, itchy, lumpy rash or other skin reactions such as red rash on your face or forehead
 - Skin rash or bruising
 - Blotches on your skin and cold extremities
 - Nail problems (e.g. loosening or separation of a nail from its bed)
 - Musculoskeletal rigidity or not being able to move your jaw (tetany)
 - Weakness or cramps in your muscles
 - Reduced sexual desire in men or women

- Blood in your water (urine). This could be a sign of a kidney problem (interstitial nephritis).
- More sugar than usual in your water (urine)
- An increased number of certain white blood cells (eosinophilia) found during a blood test
- Blood tests showing too few blood cells in your blood (pancytopenia)
- Blood tests showing a change in the amount of salts such as sodium, calcium, magnesium and chloride in your blood
- Slowed or impaired reactions
- Change in the way things smell
- Difficulty breathing or worsening of asthma

If you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE Triltec® Plus

Keep out of reach and sight of children.

Do not store above 25°C.
Store in the original package. Do not refrigerate.
Do not use Triltec® Plus tablets after the expiry date stated on the carton and the blisters. The expiry date refers to the last day of that month.

6. FURTHER INFORMATION

What Triltec® Plus contains

Triltec® Plus 5/12.5 mg contains 5 mg Ramipril and 12.5 mg Hydrochlorothiazide.
Triltec® Plus 10/12.5 mg contains 10 mg Ramipril and 12.5 mg Hydrochlorothiazide.
Triltec® Plus 5/25 mg contains 5 mg Ramipril and 25 mg Hydrochlorothiazide.
Excipients: Hydroxypropylmethylcellulose; Microcrystalline cellulose; Pregelatinized starch and Sodium stearyl fumarate; D&C yellow #10 (for Triltec® Plus 5/12.5 mg); FD&C blue #2 (for Triltec® Plus 10/12.5 mg).

What Triltec® Plus looks like and contents of the pack

Triltec® Plus is formulated for oral administration of Ramipril and Hydrochlorothiazide.
Triltec® Plus 5/12.5 mg is available as yellow, biconvex, round tablets, scored on one side, engraved “ALG TP17.5” on the other.
Triltec® Plus 10/12.5 mg is available as blue, biconvex, round tablets, scored on one side, engraved “ALG TP22.5” on the other.
Triltec® Plus 5/25 mg is available as white, biconvex, round tablets, scored on one side, engraved “ALG TP30” on the other.
Triltec® Plus 5/12.5 mg, 10/12.5 mg and 5/25 mg, are available each in packs of 30 tablets.

Not all strengths might be marketed.

For more information about this medicinal product, please contact:

Algorithm SAL
Tel: +961-9-222050

To report any side effect:

Lebanon and all MENA countries

Algorithm SAL
Fax: +961-9-222141
Email: pharmacovigilance@blgx.net
Website: www.algorithm-lb.com

Saudi Arabia

Also contact:
National Pharmacovigilance Center (NPC)
Fax: +966-1-210-7398
Email: npc.drug@sfd.gov.sa
Website: www.sfd.gov.sa/npc

Other GCC states

Also contact the relevant competent authority.

This is a medication

- A medicament is a product which affects your health, and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor’s prescription, the method of use and the instructions of the pharmacist who sold you the medicament.
- The doctor and the pharmacist are experts in medicine, its benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed.
- Do not repeat the same prescription without consulting your doctor.

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