TOZAAR PLUS LS

Losartan Potassium / Hydrochlorothiazide (50mg / 12.5mg)

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What Tozaar Plus LS is used for

It is used for:

- Treatment of hypertension, for patients in whom combination therapy is appropriate.
- Reduce the risk of stroke in patients with hypertension and left ventricular hypertrophy (thickening of the ventricular walls (lower chambers) in the heart).

How Tozaar Plus LS works

Losartan is in a group of medicines known as angiotensin-II receptor antagonists. Angiotensin-II is the hormone that binds to the receptor in blood vessels, which results in narrowing of blood vessels and subsequently raises blood pressure. Losartan inhibits the binding of angiotensin-II to these receptors. Hydrochlorothiazide is a thiazide diuretic that acts directly on the kidney to increase water excretion and thus decrease blood volume and pressure of the blood vessels.

Before you use Tozaar Plus LS

- *When you must not use it*

Do not take Losartan-HCTZ if you:

- Are allergic (hypersensitive) to Losartan Potassium, Hydrochlorothiazide or any other ingredients in this medicine.
- Experienced absence of urine (anuria).
- If you are pregnant, trying to get pregnant or think you may be pregnant.
- If you are breast-feeding.

Pregnancy and lactation

You must tell your doctor if you think you are (or might become) pregnant. Tozaar Plus LS is not recommended in early pregnancy, and must not be taken if you are more than 3 months pregnant, as it may cause serious harm to your baby if used at that stage.

Do not take Tozaar Plus LS if you are breast-feeding.

Ask your doctor or pharmacist for advice before taking any medicine.

- *Before you start use it*

Tell your doctor or pharmacist if you:

- Have liver or kidney impairment.
- Have history of angioedema (swelling of face, eyes, lips, tongue).
- Are taking diuretics (drug that tends to increase discharge of urine).
- Have signs of fluid and electrolyte imbalance (high calcium or low potassium levels or you are on a low potassium diet).
- Have gout and/or diabetes.
- Have an autoimmune disorder (SLE, Systemic lupus erythematosus).
- Have or have had an allergic condition, asthma or a condition that causes joint pain, skin rashes and fever (systemic lupus erythematosus)
- Have or have had severe vomiting and/or diarrhoea
- if you experience breathing or lung problems (including inflammation or fluid in the lungs) following hydrochlorothiazide intake in the past. If you develop any severe shortness of breath or difficulty breathing after taking Tozaar, seek medical attention immediately.

Inform your healthcare providers before taking Tozaar Plus LS if you have had skin cancer or if you develop an unexpected skin lesion during the treatment. Treatment with hydrochlorothiazide, particularly long-term use with high doses, may increase the risk of some types of skin and lip cancer (non-melanoma skin cancer). Protect your skin from sun exposure and UV rays while taking Tozaar Plus LS.

- *Taking other medicines*

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from a pharmacy, supermarket or health food shop. Preparations containing lithium should not be taken with Tozaar Plus LS without close supervision by your doctor.

Special precautionary measures (e.g. blood tests) may be appropriate if you take potassium supplements, potassium-containing salt substitutes or potassium-sparing medicines, other diuretics ("water tablets"), It is also important for your doctor to know if you are taking:

- Corticosteroids.
- Pain killers.
- Drugs for treatment of fungal infections, such as Fluconazole etc.
- Arthritis medicines.
- Resins used for high cholesterol, such as cholestyramine.
- Medicines which relax your muscles, such as tubocurarine etc. 'Pressor amines' such as norepinephrine or other drugs from the same group.
- Oral agents for diabetes or insulins.

How to use Tozaar Plus LS

- *How much to use*

Hypertension:

- Usual starting & maintenance dose: 1 tab of Tozaar Plus 50/12.5 mg once daily. May be increased to 2 tabs of Tozaar Plus 50/12.5 mg once daily

Maximum: 2 tab of Tozaar Plus 50/12.5 mg once daily.

Hypertensive patients with left ventricular hypertrophy (thickening of left ventricle):

Usual starting dose: 50 mg Losartan once daily may be titrated with a combination of losartan and hydrochlorothiazide 12.5mg, increased if necessary to Losartan 100mg and hydrochlorothiazide 25mg once daily.

- *When to use it*

Use as directed by your doctor or pharmacist.

- *How long to use it*

Continue taking Tozaar Plus LS for as

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long as your doctor recommends.

- *If you forget to use it*

Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose. Do not take a double dose to make up for the missed dose

- *If you use too much (overdose)*

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

While you are using it

- *Things you must do*
  - Take your medicine exactly as your doctor has told you.
  - Tell all the doctors, dentists and pharmacists treating you that you are taking Tozaar Plus LS.
  - Tell your doctor immediately if you become pregnant while taking this medication.

- *Things you must not do*
  - Do not stop taking the medicine unless advised by your doctor.
  - Do not take any new medicines without consulting your doctor.
  - Do not give Tozaar Plus LS to anyone else, even if they have the same symptoms or condition as you.

- *Things to be careful of*

Driving and using machines

This medicine may affect your ability to drive or use machines. If the tablets make you feel sick, dizzy or tired, or give you a headache, do not drive or use machines and contact your doctor immediately.

Side effects

Like all medicines Tozaar Plus LS can cause side effects, although not everybody gets them.

Visit your doctor or pharmacist immediately if you experience any side effects after taking this medicine.

- Cough, upper airway infection, congestion in the nose, sinusitis, sinus disorder.
- Diarrhoea, abdominal pain, nausea, indigestion.
- Muscle pain or cramps, leg pain, back pain.
- Insomnia (sleep disorder or difficulty sleeping), headache, dizziness.
- Weakness, tiredness, chest pain.
- Increased potassium levels (which can cause an abnormal heart rhythm).
- Anaemia, red or brownish spots on the skin (sometimes especially on the feet, legs, arms and buttocks, with joint pain, swelling of the hands and feet and stomach pain), bruising, reduction in white blood cells, clotting problems, reduced number of platelets.
- Changes in kidney function including kidney failure.
- Loss of appetite, increased uric acid levels or gout, increased blood sugar levels, abnormal blood electrolyte levels.
- Anxiety, nervousness, panic disorder (recurring panic attacks), confusion, depression, abnormal dreams, sleep disorders, sleepiness, memory impairment.
- Pins and needles or similar sensations, trembling, migraine, fainting.
- Blurred vision, burning or stinging in the eyes, conjunctivitis, worsening eyesight, seeing things in yellow.
- Ringing, buzzing, roaring or clicking in the ears, vertigo.
- Low blood pressure, which may be associated with changes in posture (feeling light-headed or weak when you stand up, angina (chest pain), abnormal heartbeat, cerebrovascular accident (TIA, "mini-stroke"), heart attack, palpitations.
- Inflammation of blood vessels, which is often associated with a skin rash or bruising.
- Sore throat, breathlessness, bronchitis, Pneumonitis (inflammation of lung tissues), water in the lungs (which causes difficulty breathing), nosebleed, runny nose, congestion.
- Constipation, stomach upsets, stomach spasms, vomiting, dry mouth, inflammation of a salivary gland (Sialadenitis), toothache (dental pain).
- Jaundice (yellowing of the eyes and skin), inflammation of the pancreas.
- Hives, itching, inflammation of the skin, rash, redness of the skin, sensitivity to light, dry skin, flushing, sweating, hair loss.
- Pain in the arms, shoulders, hips, knees or other joints, joint swelling, stiffness, muscle weakness.
- Swelling of the face, localised swelling (oedema), fever.
- Frequent urination including at night, abnormal kidney function including inflammation of the kidneys, urinary tract infection, sugar in the urine.
- Decreased sexual urge, impotence.

Frequency 'not known': Skin and lip cancer (Non-melanoma skin cancer).

Frequency `not known':

- Choroidal effusion: an abnormal building of liquid in your eye that may result in vision changes;
- Acute myopia: sudden nearsightedness or blurred vision;
- Acute angle-closure glaucoma: a rapid increased pressure in your eyes, eye pain. If left untreated, it may lead to permanent vision loss.

Very rare

- Acute respiratory distress (sign include severe shortness of breath, fever, weakness and confusion)

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of Tozaar Plus LS

- *Storage*

Store below 30ºC.

- *Disposal*

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of

medicines no longer required. These measures will help to protect the environment.

Product Description

- *What it looks like*
  - Light Yellow colored, oval shaped, biconvex film coated tablets with break line on both the sides

- *Ingredients*

Active ingredient(s):

- Losartan Potassium.
- Hydrochlorothiazide.

Inactive ingredients:

- Cellulose Microcrystalline.
- Lactose anhydrous.
- Starch Pregelatinized.
- Colloidal silicon dioxide.
- Talc.
- Magnesium Stearate.
- Hypromellose.
- Hydroxypropyl cellulose.
- Titanium dioxide.
- Spectracol Quinoline Yellow LK E104.

- *MAL number:*

MAL10070588AZ

Manufacturer

TORRENT PHARMACEUTICALS LTD.
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Product Registration Holder

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