ZOSAAR HCT TABLET

Losartan Potassium 10mg and Hydrochlorothiazide 12.5mg

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What Zosaar HCT is used for

The name of your medicine is Zosaar HCT Tablet (called "Zosaar HCT" in this leaflet). Zosaar HCT contains 2 prescription medicines, losartan potassium and hydrochlorothiazide. It is used to:

- lower high blood pressure (hypertension). Zossar HCT is not used for initial treatment of high blood pressure.
- lower the chance of stroke in patients with high blood pressure and a heart problem (such as enlargement to the walls of the left chamber of the heart). But this may not apply to Black patients.

How Zosaar HCT works

Zosaar HCT combines losartan potassium, an angiotensin II receptor (type AT1) antagonist and hydrochlorothiazide, a diuretic.

Zosaar HCT relax your blood vessels so your blood pressure is lower. The hydrochlorothiazide ingredient in Zosaar HCT works by making your kidneys pass more water and salt.

Before you use Zosaar HCT

-When you must not use it

Do not take this medicine and tell your doctor if

- You are allergic to losartan, potassium, hydrochlorothiazide orany of the other ingredients of Zosaar HCT (listed in Section 9 below).
- You are allergic to any sulfonamide-containing ("sulfa") medicines. Ask your doctor if youare not sure what sulfonamide- containing ("sulfa") medicines are.
- You are not passing urine.

-Before you start to use it

Check with your doctor or pharmacist before taking this medicine:

- If you are pregnant or planning to become pregnant.
- If you are breast feeding. You should choose to bottle feed your baby or not take Zosaar HCT.
- You are above 60 years old.
- If you have kidney and liver problems
- If you have been vomiting (throwing up), having diarrhea, sweating a lot, or not drinking enough fluids. These could cause you to have low blood pressure
- If you have systemic lupus erythematosus (Lupus; SLE)
- If you have diabetes
- If you have asthma
- If you have any other allergies
- 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 Zosaar HCT, seek medical attention immediately.

Inform your healthcare providers before taking Zosaar HCT if you havehad 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 Zosaar HCT.

-Taking other medicines

Tell your doctor about all the medicines you take, including prescription and non-prescription medicines, vitamins, and herbal supplements.

Zosaar HCT and certain othermedicines may interact with each other. Especially tell your doctor if you are taking:

- potassium supplements
- Rifampin
- Fluconazole
- Salt substitutes containing potassium
- Diuretics
- Lithium
- medicines used to treat pain and arthritis, called non-steroidal anti-inflammatory drugs (NSAIDs), including COX-2 inhibitors.
- Alcohol
- Barbiturates
- Narcotics
- Oral anti-diabetic drugs and insulin
- Anti-hypertensive drugs
- Cholestyramine and colestipolresin
- Steroids
- Glycyrrhizin(found in liquorice)
- Pressor amines
- Muscle relaxants

How to use Zosaar HCT

-How much to use

The usual starting dose is one tablet, once daily, with maximum dose of 2 tablets daily.

However, depending on your doctor's finding, the dose may be reduced or increased. Hence, always take Zosaar HCT as directed by your doctor.

Your doctor may do urine and blood tests from time to time while you are taking Zosaar HCT.

Zosaar HCT may be administered with other antihypertensive agents.

-When to use it

ZOSAAR HCT can be taken with other anti-hypertensive drugs, and can be taken with or without food

-How long to use it

The time period for taking ZOSAAR HCT depends on your doctor's instruction.

-If you forget to use it

If you miss a dose, take it as soon as you remember. If it is close to your next dose, do not take the missed dose. Just take the next doseat your regular time.

-If you take too much (overdose)

If you take too much ZOSAAR HCT, call your doctor or Poison Control Center, or go to the nearest hospital emergency room right away.

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While you are using Zosaar HCT

-Things you must do

- Swallow the tablets whole with a glass of water
- Take your dose at same time of the day
- Never take 2 doses in 1 day unless instructed by your doctor.
- Keep taking Zosaar HCT until the treatment is finished, even if you feel better.

If you have any further questions onthe use of this product, ask your doctor or pharmacist.

-Things you must not do

Do not stop your medication without consulting your doctor.

-Things to be careful of

- If you have liver problems the dose might be lowered. You may have more frequent blood tests to see how your liver is working.
- Pregnancy and breast-feeding: ask your doctor or pharmacist for advice before taking any medicine if you think you might be or if you are pregnant or if you are breastfeeding.
- Inform your doctor if you have are old (above 60 years) or taking any other medicines, especially sulpha drugs, anti-hypertensive and diuretics.

Side effects

Zosaar HCT may cause the following side effects that may be serious:

- injury or death of unborn babies.
- allergic reaction. Symptoms of an allergic reaction are swelling of the face, lips, throat, or tongue. Get emergency medical help right away and stop taking Zosaar HCT.
- Low blood pressure (hypotension) which may cause you to feel faint or dizzy. Lie down if you feel faint or dizzy. Call your doctor right away.
- Systemic lupus erythematosus (also known as Lupus; SLE)
- If you already have kidney problems, you may see a worsening in how well your kidneys work. Call your doctor if you get swelling in your feet, ankles, or hands, or unexplained weight gain.
- If you already have liver problems, you may see a worsening in how well your liver works. Call your doctor if you get nausea, pain in the right upper stomach area (abdomen), yellow eyes or skin (which can be itchy).

The following side effects have been reported:

- Fatigue
- Diarrhea
- Nausea
- Headache
- inflammation of the respiratory tract
- sore throat (inflammation)

Frequency 'not known':

- Skin and lip cancer (Non melanoma skin cancer)
- Choroidal effusion: an abnormal building of liquid in your eye that may result in vision changes;
- Acute myopia: sudden near sightedness 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 (signs include severe shortness of breath, fever, weakness and confusion).

Tell your doctor if you get any side effect that bothers you or that won't go away.
This is **not** a complete list of side effects. For a complete list, ask 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 Zosaar HCT

Storage:

- Keep out of the reach and sight of children.
- Do not use Zosaar HCT after the expiry date refers to the last day on the carton. The expiry date refers to the last day of that month.
- Store in the original pack in a dry place at or below 30°C.
- Do not use Zosaar HCT if the tablets are chipped or there are other visible signs of deterioration.

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 helps to protect the environment.

Product Description

-What it looks like:

Zosaar HCT F.C Tablet is an oval shaped, biconvex, yellow film coated tablet; engraved with CCP on one side, with 135 on the other side.

-Ingredients in Zosaar HCT

Active ingredients:

Losartan potassium, hydrochlorothiazide

Inactive ingredients:

Pregelatinized starch, Microcrystalline Cellulose, Lactose,
Povidone K30, Magnesium stearate, Hydroxypropyl Methyl Cellulose E6, Titanium dioxide, D&C Yellow No. 10

***-MAL number*:** MAL16045051ACZ

Manufacturer

China Chemical & Pharmaceutical Co. Ltd.
No. 182-1, Keng Tze Kou, Hsinfong Shiang, Hsinchu County 304, Taiwan R.O.C.

Product Registration Holder

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No. 2, Jalan SS 13/5, 47500 Subang Jaya, Selangor, Malaysia

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