

VALZAAR H TABLETS

Valsartan and Hydrochlorothiazide (160mg+12.5mg)

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What VALZAAR H is used for

VALZAAR H is a prescription medicine used in adults to lower high blood pressure (hypertension).

How VALZAAR H works

VALZAAR H belongs to a class of medicines which help to control high blood pressure. VALZAAR H works by blocking the effect of angiotensin II which cause increase in blood pressure. As a result, blood vessels relax and blood pressure is lowered.

Before you use VALZAAR H

When you must not use it

Do not take VALZAAR H:

- If you are allergic (hypersensitive) to valsartan or hydrochlorothiazide or any of the other ingredients of VALZAAR H.
- If you have severe liver disease.

Pregnancy and lactation

Do not take VALZAAR H if you are pregnant, trying to get pregnant or think you may be pregnant. If you get pregnant while taking VALZAAR H, stop taking it immediately and contact your doctor.

Do not take VALZAAR H if you are breast-feeding. Ask your doctor or pharmacist for advice before taking any medicine.

Before you start to use it

You must be especially careful and talk to your doctor before taking VALZAAR H if any of the following apply to you.

- If you have liver disease.
- If you have severe kidney disease or if you are undergoing dialysis.

- If you are suffering from a narrowing of the kidney artery.
- If you have recently undergone kidney transplantation (received a new kidney).
- If you are being treated after a heart attack or for heart failure. Your doctor may check your kidney function.
- If you have autoimmune disease (immune system attacking healthy body cells and tissues), swelling or edema, severe heart disease.
- If you have a condition of increased pressure within the eyeball (glaucoma).
- If you have lost a lot of fluid (dehydration) caused by diarrhoea, vomiting, or high doses of water pills (diuretics).
- The use of VALZAAR H in children and adolescents below the age of 18 years is not recommended.
- 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 Valzaar H, seek medical attention immediately.

Inform your healthcare providers before taking VALZAAR H 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 VALZAAR H.

Taking 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.

The effect of the treatment can be influenced if VALZAAR H is taken together with certain other medicines. It may be necessary to change the dose, to take other precautions, or in some cases to stop taking one of the medicines. This applies to both prescription and non-prescription medicines, especially:

- Medicines that increase the amount of potassium in your blood. These include potassium supplements or salt substitutes containing potassium, potassium-sparing

medicines and heparin (blood thinner medicine).

- Certain type of pain killers called nonsteroidal anti-inflammatory medicines (NSAIDs).
- Lithium, a medicine used to treat some types of psychiatric illness.
- Aliskiren, a medicine used to treat high blood pressure.
- Rifampin and amphotericin (medicine used to treat infections).
- Ciclosporin.
- Allopurinol, medication used primarily to treat excess uric acid in the blood.
- Anticancer medicines such as cyclophosphamide and methotrexate.
- Thiazide, muscle relaxant.
- Anti-diabetic agent – may change glucose level.
- Amantadine.
- Atropine, biperin.
- Vitamin D.
- Calcium salt.
- Diazoxide.
- Methyldopa.
- Alcohol, barbiturate, or narcotics.
- Pressor amines.
- Medicinal products affecting serum potassium level such as corticosteroids, amphotericin, carbenoxolone and penicillin G.

How to use VALZAAR H

How much to use

- The recommended dose is 1 tablet per day.
- Always take VALZAAR H exactly as your doctor has told you in order to get the best results and reduce the risk of side effects.
- You should check with your doctor or pharmacist if you are not sure.
- People with high blood pressure often do not notice any signs of this problem. Many may feel quite normal. This makes it all the more important for you to keep your appointments with the doctor even if you are feeling well

When to use it

- You can take VALZAAR H with or without food. Swallow VALZAAR H with a glass of water.
- Take VALZAAR H at about the same time each day. Make sure you have at least 7-8 hours for sleep after taking this medicine.

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- How long to use it

Ask your doctor or pharmacist how long you can take it. Do not initiate or stop the treatment without consulting your doctor. Stopping your treatment with VALZAAR H may cause your disease to get worse. Do not stop taking your medicine unless your doctor tells you to.

- If you forget to use it

Consult your doctor or pharmacist on what you should do if you forget to use Valzaar H.

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.

If you experience severe dizziness and/or fainting, lie down and contact your doctor immediately.

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 that are treating you that you are taking VALZAAR H.
- 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 Valzaar H 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, VALZAAR H can cause side effects, although not everybody gets them.

Very Common:

- Hypokalaemia (low level of potassium in blood).
- Blood lipids increased (mainly at higher doses).

Common:

- Hyponatraemia (low sodium level in the blood).
- Hypomagnesaemia (abnormally low levels of magnesium in blood).
- Hyperuricaemia (excess of uric acid in the blood).
- Postural hypotension (occurs when a person's blood pressure falls when suddenly standing up from a lying or sitting position).
- Loss of appetite
- Mild nausea
- Vomiting
- Urticaria (raised, itchy rash that appears on the skin) and other forms of rash.
- Impotence.

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.

Frequency 'not known':

- Skin and lip cancer (Non-melanoma skin cancer).

Very rare

- Acute respiratory distress (signs 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 VALZAAR H

- Storage

- Store below 30°C.

- 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

Pink colored, oval shaped, beveled edge, biconvex, film coated tablets debossed with "1072" on one side and plain on other side.

Ingredients

Active ingredients:

- Valsartan.
- Hydrochlorothiazide.

Inactive ingredients

- Lactose Monohydrate DCL-11.
- Croscarmellose Sodium.
- Povidone (K-30).
- Purified Water.
- Magnesium Stearate.
- Talc.
- Hypromellose 2910 (6cps).
- Titanium Dioxide.
- Polyethylene Glycol 400.
- Ferric Oxide Red.
- Isopropyl Alcohol.
- Methylene Chloride.

- MAL number:

MAL17107011AZ

Manufacturer

TORRENT PHARMACEUTICALS LTD.
Indrad 382 721, District: Mehsana INDIA.

Product Registration Holder

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