

ZYLTAN H TABLET

Losartan Potassium 50 mg and Hydrochlorothiazide 12.5 mg Tablets USP

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What ZYLTAN H is used for

ZYLTAN H is used for the treatment of high blood pressure (hypertension) in patients requiring both losartan and hydrochlorothiazide. This fixed dose combination is not indicated for initial therapy of hypertension, except when the hypertension is severe enough that the value of achieving prompt blood pressure control exceeds the risk of initiating combination therapy in these patients. Also it is used to reduce the risk of stroke in patients with hypertension and left ventricular hypertrophy (enlargement of the walls of the left chamber of the heart).

How ZYLTAN H works

ZYLTAN H is a combination of an angiotensin II receptor antagonist (losartan) and a diuretic (hydrochlorothiazide). Losartan and hydrochlorothiazide work together to lower hypertension. Losartan lowers blood pressure by blocking angiotensin II. Angiotensin II normally tightens your blood vessels. The losartan allows them to relax. Hydrochlorothiazide works by making your kidneys pass more water and salt.

Before you use ZYLTAN H

- When you must not use it
- Do not take ZYLTAN H; if you have an allergy to any ingredients of ZYLTAN H or sulfonamide or sulfur medicines. If you are not passing urine. If the expiry date printed on the pack has passed.

Pregnancy and lactation

Do not take ZYLTAN H if you are pregnant, trying to get pregnant or think you may be pregnant.

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

- Before you start to use it

Tell your doctor; if you intend to become pregnant or plan to breast-feed. If you have any medical conditions. If you have recently had excessive vomiting or diarrhea. If you have allergies to any medicines or substances.

- 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. Your doctor or pharmacist has more information on medicines to be careful with or to avoid while taking ZYLTAN H.

How to use ZYLTAN H

- How much to use

Your doctor will tell you how many tablets you need to take each day. This depends on your condition and whether you are taking other medicines. For most patients, the usual dose is one tablet of ZYLTAN H once a day. Depending on your condition, the dose may need to be increased to two tablets of ZYLTAN H once a day.

Follow all directions given to you by your doctor and pharmacist carefully. They may differ from the information contained in this leaflet. If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

- When to use it

- You can take Zyltan H before or after food.
- Take ZYLTAN H at about the same time each day. It will also help you remember when to take the tablets. Use as directed by your doctor or pharmacist.

- How long to use it

ZYLTAN H must be taken every day. Continue taking ZYLTAN H for as long as your doctor recommends.

- If you forget to use it

Consult your doctor or pharmacist on what you should do 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. Taking too many tablets may cause a drop in blood pressure, irregular heartbeat due to agitation and slow pulse.

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 ZYLTAN H. Tell your doctor immediately if you become pregnant while taking this medication.

If you feel light-headed, dizzy or faint when getting out of bed or standing up, get up slowly. If you have excessive vomiting and/or diarrhea while taking ZYLTAN H, or you have any symptoms like dry mouth, thirst, weakness, tiredness, drowsiness, muscle pains or cramps, fast heart beat, passing less urine than normal. Make sure you drink enough water during exercise and hot weather when you are taking ZYLTAN H, especially if you sweat a lot. If you do not drink enough water while taking ZYLTAN H, you may faint or feel light-headed or sick.

- 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 ZYLTAN 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. If you drink alcohol, or take strong pain killers or barbiturates, the effects may be worse.

Side effects

Like all medicines, ZYLTAN H can cause side effects, although not everybody gets them. Visit your doctor or pharmacist immediately if you experience any of the following side effects after taking this medicine;

Nausea, vomiting, cramping, constipation, restlessness, headache, weakness, dizziness, fatigue, taste alteration, transient blurred vision, cough, rash, dermatitis, increased sensitivity of the skin to sun, diarrhea, jaundice, swelling of the face, lips, mouth, throat or tongue which may cause difficulty in swallowing or breathing, shortness of breath and severe skin reaction.

Other side effects not given above may also occur in some patients. Consult your doctor/ pharmacist for further information.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website

portal.bpfk.gov.my

(Consumers → Reporting).

Storage and Disposal of ZYLTAN H

- Storage

Keep out of the reach and sight of children. Store below 30°C and protected from light.

- 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

Reddish brown coloured, oblong shaped, film coated tablet having a break line on one side.

- Ingredients

- Active ingredient(s)
Losartan Potassium and
Hydrochlorothiazide

- Inactive ingredients
Croscarmellose Sodium,
Microcrystalline Cellulose, Sodium
Starch Glycolate, Magnesium
Stearate, Talc, Ethyl Cellulose,
Ferric Oxide Red, Hydroxy Propyl
Methyl Cellulose 2910 (E15),
Isopropyl Alcohol, Methylene
Chloride, Propylene Glycol,
Titanium Dioxide.

- MAL number(s):

- MAL13065036A

Manufacturer

Troikaa Pharmaceuticals Ltd.
C-1, Sara Industrial Estate, Selaqui,
Dehradun, Uttarakhand, India.

Product Registration Holder

Medispec (M) Sdn Bhd (137156-U)
Lorong Sempadan 2,
(Off Boudry Road), 11400 Ayer Itam,
Penang, Malaysia

Date of revision

-18/12/2013