

PRESARTAN H 50/12.5MG FILM COATED TABLET

Losartan Potassium (50mg) & Hydrochlorothiazide (12.5mg)

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- if you have had gout
 - if you have or have had severe vomiting and/or diarrhea
 - if you have narrow arteries to your kidneys (renal artery stenosis)
 - if you have previously suffered from swelling of the face, lips, throat or tongue
 - if you take diuretics
 - if you have or have had an allergic condition, asthma or a condition that causes joint pain, skin rashes and fever (systemic lupus erythematosus)
 - if you have high calcium or low potassium levels or you are on a low potassium diet
 - if you are going to have tests to check your parathyroid function
 - If you have liver impairment
 - if you have renal impairment
 - Resins used for high cholesterol, such as colestyramine, colestipol
 - Medicines which relax your muscles
 - Steroids
 - 'Pressor amines' such as adrenaline or other drugs from the same group.
 - Medicines for diabetes (oral agents, insulin)
 - Barbiturates, narcotics
 - Drugs for treatment of fungal infections

What Presartan H 50 is used for

Presartan H 50 is indicated for the treatment of essential hypertension (high blood pressure).

Presartan H 50 is a combination of an angiotensin II receptor antagonist (losartan) and a diuretic (hydrochlorothiazide).

How Presartan H 50 works

It is a medicine used to treat high blood pressure. Losartan relaxes your blood vessels and thus lowers your blood pressure, whereas hydrochlorothiazide works by making your kidneys pass more water and salt.

Before you use Presartan H 50

When you must not use it

You should not take this medicine when:

- you are allergic (hypersensitive) to losartan, hydrochlorothiazide or to any of the other ingredients in this medicine
- you are allergic (hypersensitive) to other sulfonamide-derived substances (e.g. other thiazides, some antibacterial drugs such as cotrimoxazole, ask your doctor if you are not sure)
- you are, think you may be or are planning to become pregnant
- You have severe renal problem

Before you start to use it

Check with your doctor before you take losartan and hydrochlorothiazide tablets:

- if you are diabetic

Inform your doctor if you are taking any other medicines, including those available to buy without a prescription, herbal and complementary medicines or have allergic reaction to any medicines. Also tell your doctor if you are allergic to any other substances such as food, preservatives or dyes.

Taking other medicines

Presartan H 50 and certain other medicines may interact with each other. Please tell your doctor if you are taking or have recently taken any other medicines, including medicines obtained without a prescription, vitamins and herbal supplements.

Especially tell your doctor if you are taking:

- Lithium (a medicine used to treat certain kind of depression)
- Potassium supplements, potassium containing salt substitutes or potassium-sparing diuretics
- Other medicines to reduce your blood pressure
- Pain killers and arthritis medicines

How to use Presartan H 50

How much to use

The usual dose of Presartan H 50 for most patients with high blood pressure is 1 tablet per day to control blood pressure over the 24-hour period. This can be increased to maximum of 2 tablets once daily.

When to use it

Presartan H 50 may be taken with or without food. Your doctor will prescribe you the exact dosage to be taken depending on your condition and whether you are taking other medicines. Take your medication exactly as directed by your doctor.

How long to use it

Take this medicine for as long as your doctor tells you to. It is important to continue taking Presartan H 50 for as long as your doctor prescribes it in order to maintain smooth control of your blood pressure.

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 dose at your regular time.

If you use too much (overdose)

If an overdose has been taken there may be signs such as a drop in blood pressure, palpitations, slow pulse, electrolyte depletion, and dehydration. If you (or someone else) swallow a lot of

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the tablets at the same time, contact your doctor immediately so that medical attention may be given promptly.

While you are using it

Things you must do

- Keep Presartan H 50 tablets out of the reach and sight of children in a secure place.
- Do not use Presartan H 50 tablets after the expiry date which is stated on the container. The expiry date refers to the last day of that month.
- Store the tablets in the original package.
- Inform your doctor if you are pregnant or trying for a baby or breast-feeding

Consult your doctor:

- If you have any questions regarding the medication.
- If you are taking any additional medications
- If any of the side effects get serious, or if you notice any side effects not listed in this leaflet
- If you become pregnant while on losartan potassium and hydrochlorothiazide tablets, tell your doctor immediately. A switch to a suitable alternative treatment should be carried out in advance of a planned pregnancy.
- In case you have taken losartan potassium and hydrochlorothiazide tablets more than the recommended dose, consult your doctor.

Things you must not do

- When you begin treatment with this medication, you should not perform tasks which may require special attention (for example, driving an automobile or operating dangerous machinery) until you know how you tolerate your medicine.
- Do not stop the drug, without taking the advice of your doctor.

- Remember that this medicine is for you only. Never give it to anyone else. It may harm them, even if their symptoms are the same as yours.

Things to be careful of

You are advised not to drink alcohol whilst taking these tablets: alcohol and losartan potassium and hydrochlorothiazide tablets may increase each other's effects.

Side effects

Like all medicines, Presartan H 50 tablets can cause side effects, although not everybody gets them. The most common side effects of losartan potassium and hydrochlorothiazide tablets are abdominal pain, swelling, fast or irregular heartbeat (palpitations), back pain, dizziness, cough, stuffy nose, "colds" (upper respiratory infection) and rash.

Tell your doctor if you notice or are worried by any of the side effects listed or notice any other effects not listed. This is not a complete list of side effects. For a complete list, ask your doctor or pharmacist.

Losartan potassium and hydrochlorothiazide tablets may cause the following side effects that may be serious:

- Injury or death of unborn babies
- A severe allergic reaction (rash, itching, swelling of the face, lips, mouth or throat that may cause difficulty in swallowing or breathing), stop taking Presartan H 50 tablets and tell your doctor immediately or go to the casualty department of your nearest hospital.
- Low blood pressure (hypotension). Low blood pressure may cause you to feel faint or dizzy. Lie down if you feel faint or dizzy. Call your doctor right away.
- A new or worsening condition called systemic lupus erythematosus (where the own

body immune system attack itself and cause rashes).

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 Presartan H 50

Storage

Store below 30°C in a dry place.

Disposal

Medicines should not be disposed of via waste water 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

Yellow coloured, oval, biconvex, film coated tablets. Blister of 14 tablets, 2 such Blisters in a printed showbox along with a leaflet.

Ingredients

Active ingredient:

Losartan Potassium USP..... 50mg
Hydrochlorothiazide BP12.5 mg

Inactive ingredient

Lactose Monohydrate BP, Microcrystalline cellulose BP (Avicel pH 101), Pregelatinised starch BP, Purified water BP, Maize starch (Dried) IHT, Colloidal Anhydrous Silica BP, Magnesium stearate BP, Hydroxy Propyl Methyl Cellulose BP(15 cps), Titanium dioxide BP, Purified talc BP, Macrogol (PEG 6000) BP, Quinoline yellow Lake IHT

MAL No.: MAL11040023A

Manufacturer

Ipca Laboratories Ltd.
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Mumbai 400 067, India.

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Product Registration Holder

LF Asia (Malaysia) Sdn Bhd (719-V)
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Selangor Darul Ehsan

Date of Revision

19/07/2013