

UNIZAR - H

LOSARTAN POTASSIUM & HYDROCHLOROTHIAZIDE TABLETS

Composition

Each film-coated tablet contains:

Losartan potassium USP 50 mg

Hydrochlorothiazide BP 12.5 mg

Colours: Sunset yellow & Titanium Dioxide USP

Description

Losartan potassium, is an angiotensin II receptor, is chemically described as 2-butyl-4-chloro-1-[p-(o-1H-tetrazol-5-ylphenyl)benzyl]imidazole-5-methanol monopotassium salt. Losartan potassium is a white to off-white free-flowing crystalline powder. It is freely soluble in water, soluble in alcohols, and slightly soluble in common organic solvents, such as acetonitrile and methyl ethyl ketone.

Hydrochlorothiazide is a diuretic. Chemically it is describe as 6-chloro-3,4-dihydro-2H-1,2,4-benzothiadiazine-7-sulfonamide 1,1-dioxide. It is a white or almost white, crystalline powder, very soluble in water, soluble in acetone, sparingly soluble in alcohol. It dissolve in dilute solution of alkali hydroxides.

Pharmacology

Angiotensin II [formed from angiotensin I in a reaction catalyzed by angiotensin converting enzyme (ACE, kininase II)], is a potent vasoconstrictor, the primary vasoactive hormone of the renin-angiotensin system and an important component in the pathophysiology of hypertension. It also stimulates aldosterone secretion by the adrenal cortex. Losartan and its principal active metabolite block the vasoconstrictor and aldosterone-secreting effects of angiotensin II by selectively blocking the binding of angiotensin II to the AT1 receptor found in many tissues, (e.g., vascular smooth muscle, adrenal gland). There is also an AT2 receptor found in many tissues but it is not known to be associated with cardiovascular homeostasis. Both losartan and its principal active metabolite do not exhibit any partial agonist activity at the AT1 receptor and have much greater affinity (about 1000-fold) for the AT1 receptor than for the AT2 receptor. Hydrochlorothiazide is a thiazide diuretic. Thiazides affect the renal tubular mechanisms of electrolyte reabsorption, directly increasing excretion of sodium and chloride in approximately equivalent amounts. Indirectly, the diuretic action of hydrochlorothiazide reduces plasma volume, with consequent increases in plasma renin activity, increases in aldosterone secretion, increases in urinary potassium loss, and decreases in serum potassium. The renin-aldosterone link is mediated by angiotensin II, so coadministration of an angiotensin II receptor antagonist tends to reverse the potassium loss associated with these diuretics.

Indications

Unizar- H is indicated for the treatment of hypertension. 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

Contraindications

Unizar- H is contraindicated in patients who are hypersensitive to any component of this product.

Because of the hydrochlorothiazide component, this product is contraindicated in patients with anuria or hypersensitivity to other sulfonamide-derived drugs.

Precaution and warning

When used in pregnancy during the second and third trimesters, drugs that act directly on the renin-angiotensin system can cause injury and even death to the developing fetus. When

pregnancy is detected, discontinue therapy as soon as possible.

Based on losartan component: Avoid use or use a smaller dose in patients who are volume depleted; correct depletion first. Deterioration in renal function can occur with initiation. Use with caution in unilateral renal artery stenosis and pre-existing renal insufficiency; significant aortic/mitral stenosis.

Based on hydrochlorothiazide component: Avoid in severe renal disease (ineffective). Electrolyte disturbances (hypokalemia, hypochloremic alkalosis, hyponatremia) can occur. Use with caution in severe hepatic dysfunction; hepatic encephalopathy can be caused by electrolyte disturbances. Gout can be precipitate in certain patients with a history of gout, a familial predisposition to gout, or chronic renal failure. Cautious use in diabetics; may see a change in glucose control. Hypersensitivity reactions can occur. Can cause SLE exacerbation or activation. Use with caution in patients with moderate or high cholesterol concentrations. Photosensitization may occur. Correct hypokalemia before initiating therapy.

Drug Interactions

Some medicines and Unizar-H may interfere with each other. These include: other fluid tablets (diuretic), also called water tablets, including potassium-sparing diuretics, potassium tablets, potassium-containing salt substitutes, other medicines used to treat high blood pressure, digoxin, lithium, used to treat severe mood swings and some types of depression, steroid medicines such as cortisone, prednisone, insulin and tablets used to treat diabetes, barbiturates, such as phenobarbitone, strong pain killers such as codeine, morphine, dextropropoxyphene, non-steroidal anti-inflammatory medicines (NSAIDs), cholestyramine and colestipol, used to treat high cholesterol, medicines used to relax muscles before and during surgery, medicines used in emergency situations such as adrenaline, alcohol.

Adverse Reactions

The adverse reactions to Losartan potassium include, headache, dizziness, asthenia or fatigue. Rarely angioedema, first dose hypotension, transient elevation of liver transaminases and hyperkalaemia.

The adverse reaction to hydrochlorothiazide includes, hyponatraemia, hypokalaemia, skin rash, nausea, anorexia, vomiting, epigastric discomfort, headache, paraesthesias, hyperuricaemia, fatigue and blood dyscrasias. May include hyperglycemia. Photosensitivity, hypomagnesaemia, hypercalcaemia.

Dosage & Administration

Take Unizar -H every day, exactly as your doctor has instructed. It is important to continue taking Unizar H for as long as your doctor prescribes it in order to maintain smooth control of your blood pressure.

The usual dose of Unizar- H for most patients is 1 tablet of Unizar -H 50-12.5 per day to control blood pressure over the 24-hour period.

Unizar H can be taken with or without food. For convenience and to help you remember, try to take Unizar -H at the same time each day.

Storage

Store in a dry place below 30°C & protect from light.

Keep the medicine out of the reach of children.

Presentation

Box of 1x7 tablets & 4x7 tablets.

Prescription Only Medicine

Manufactured in India by
GRACURE PHARMACEUTICALS LTD.
E-1505, BICO Industrial Area, Phase III, Bhubaneswar (Rajasthan)

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