

Size: L= 256 x W= 145 mm (Unfolded)

Osartil[®] 50 Plus Osartil[®] 100 Plus Osartil[®] 100/12.5

Losartan Potassium & Hydrochlorothiazide tablet

Presentation

Osartil[®] 50 Plus: Each tablet contains Losartan Potassium USP 50 mg and Hydrochlorothiazide BP 12.5 mg.
Osartil[®] 100 Plus: Each tablet contains Losartan Potassium USP 100 mg and Hydrochlorothiazide BP 25 mg.
Osartil[®] 100/12.5: Each tablet contains Losartan Potassium USP 100 mg and Hydrochlorothiazide BP 12.5 mg.

Description

Angiotensin II formed from angiotensin I in a reaction catalyzed by angiotensin converting enzyme (ACE), 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). *In vitro* binding studies indicate that losartan is a reversible, competitive inhibitor of the AT₁ receptor. Neither Losartan nor its active metabolite inhibits ACE (kinase II, the enzyme that converts angiotensin I to angiotensin II and degrades bradykinin); nor do they bind to or block other hormone receptors or ion channels known to be important in cardiovascular regulation.

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 co-administration of an angiotensin II receptor antagonist tends to reverse the Potassium loss associated with these diuretics.

Indications and Uses

Osartil Plus is indicated for the treatment of hypertension. It is also indicated to reduce the risk of stroke in patients with hypertension and left ventricular hypertrophy.

Dosage and Administration

Hypertension

The usual starting dose of Osartil 50 Plus is one tablet once daily. For patients who do not respond adequately to one tablet the dosage may be increased to Osartil 100 Plus once daily. A patient whose blood pressure is not adequately controlled with Losartan 100 mg monotherapy may be switched to Osartil 100/12.5 once daily. In hypertensive patients with left ventricular hypertrophy initial dose is Osartil 50 Plus, if additional blood pressure reduction is needed, Osartil 100/12.5 may be given, followed by Osartil 100 Plus if required. The maximum dose is Osartil 100 Plus once daily. In general, the antihypertensive effect is attained within three weeks after initiation of therapy.

No initial dosage adjustment of Osartil 50 Plus is necessary for elderly patients. But maximum dose of Osartil 100 Plus once daily dose should not be used as initial therapy in elderly patients.

Use in Patients with Renal Impairment: The usual regimens of therapy with Osartil 50 Plus may be followed as long as the patient's creatinine clearance is >30 ml/min. In patients with more severe renal impairment, loop diuretics are preferred to thiazides. In that case, hydrochlorothiazide is not recommended.

Use in patients with Hepatic Impairment: The combination of Losartan and Hydrochlorothiazide is not recommended for titration in patients with hepatic impairment because the appropriate 25 mg starting dose of Losartan cannot be given.

Severe Hypertension

The starting dose for initial treatment of severe hypertension is one tablet of Osartil 50 Plus once daily. For patients who do not respond adequately to this dose after 2 to 4 weeks of therapy, the dosage may be increased to Osartil 100 Plus once daily. The maximum dose is one tablet of Osartil 100 Plus once daily.

Osartil Plus may be administered with other antihypertensive agents.

Osartil Plus may be administered with or without food.

Side effects

Generally this product is well tolerated. However, few side effects including abdominal pain, swelling, back pain, dizziness, rash and cough may occur in rare cases.

Contraindications

The combination of Losartan and Hydrochlorothiazide 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.

Precautions

- Hypersensitivity: Angioedema
- Periodic determination of serum electrolytes to detect possible electrolyte imbalance should be performed at appropriate intervals
- Hypokalemia may rarely develop, especially with brisk diuresis, when severe cirrhosis is present, or after prolonged therapy
- Impaired renal function and
- Symptomatic hypotension

Use In Pregnancy and Lactation

Pregnancy: Not recommended

Nursing mother: Not recommended

Drug Interactions

Losartan Potassium

No significant drug-drug pharmacokinetic interactions have been found in interaction studies with Hydrochlorothiazide, Digoxin, Warfarin, Cimetidine and Phenobarbital. As with other drugs that block angiotensin II or its effects, concomitant use of potassium-sparing diuretics (e.g. Spironolactone, Triamterene, Amiloride), potassium supplements, or salt substitutes containing potassium may lead to increase in serum potassium. As with other antihypertensive agents, the antihypertensive effect of Losartan may be blunted by the non-steroidal anti-inflammatory drug Indomethacin.

Hydrochlorothiazide

When administered concurrently, the following drugs may interact with Thiazide diuretics: alcohol, barbiturates, or narcotics - potentiation of orthostatic hypotension may occur.

Antidiabetic drugs (oral agents and Insulin) - dosage adjustment of the antidiabetic drug may be required.

Other antihypertensive drugs - additive effect or potentiation.

Cholestyramine and colestipol resins - absorption of Hydrochlorothiazide is impaired in the presence of anionic exchange resins.

Overdosage

Losartan Potassium

Limited data are available in regard to over dosage in humans. The most likely manifestation of over dosage would be hypotension and tachycardia; bradycardia could occur from parasympathetic (vagal) stimulation. Of symptomatic hypotension should occur, supportive treatment should be instituted. Neither losartan nor its metabolite can be removed by hemodialysis.

Hydrochlorothiazide

The most common signs and symptoms observed are those caused by electrolyte depletion (hypokalemia, hypochloremia, and dehydration resulting from excessive diuresis. Of digitalis has also been administered, hypokalemia, may accentuate cardiac arrhythmias. The degree to which Hydrochlorothiazide is removed by hemodialysis has not been established.

Storage

Do not store above 30° C. Keep away from light and out of the reach of children.

Commercial Pack

Osartil[®] 50 Plus: Each box contains 5 blister strips of 10 tablets.

Osartil[®] 100 Plus: Each box contains 3 blister strips of 10 tablets.

Osartil[®] 100/12.5: Each box contains 3 blister strips of 10 tablets.

Manufactured by
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