Olpres HZ

Olmesartan Medoxomil BP & Hydrochlorothiazide USP

Composition

Olpres HZ 20/12.5 Tablet: Each film coated tablet contains Olmesartan Medoxomil BP 20 mg and Hydrochlorothiazide USP 12.5 mg.

Olpres HZ 40/12.5 Tablet: Each film coated tablet contains Olmesartan Medoxomil BP 40 mg and Hydrochlorothiazide USP 12.5 mg.

Pharmacology

Olpres HZ is a combination of Olmesartan Medoxomil and Hydrochlorothiazide, where Olmesartan Medoxomil is an angiotensin receptor antagonist (AT1 subtype) and Hydrochlorothiazide is a thiazide diuretic. Olmesartan Medoxomil blocks the vasoconstrictor effects of angiotensin II by selectively blocking the binding of angiotensin 2 to the AT1 receptor in vascular smooth muscle. Its action is therefore independent of the pathways for angiotensin 2 synthesis. Hydrochlorothiazide affects 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. Co-administration of Olmesartan Medoxomil tends to reverse the potassium loss associated with Hydrochlorothiazide.

Indication

Olpres HZ is indicated for the treatment of hypertension. Lowering blood pressure reduces the, risk of fatal and nonfatal cardiovascular events, primarily strokes and myocardial infarctions. This fixed dose combination is not indicated for initial therapy of hypertension.

Dose and administration

Olpres HZ 20/12.5 and **Olpres HZ** 40/12.5 should be taken orally with or without food. The recommended starting dose of Olpres HZ is 20/12.5 mg once daily in patients whose blood pressure is not adequately controlled with hydrochlorothiazide monotherapy or who experience dose limiting adverse reactions with hydrochlorothiazide. The recommended starting dose of **Olpres HZ** 40/12.5 mg once daily in patients whose blood pressure is not adequately controlled with Olmesartan monotherapy.

Patient with renal impairment: The usual regimens of therapy with this combination may be followed provided the patient's creatinine clearance is > 30 ml/min. In patients with more severe renal impairment loop diuretics are preferred to thiazides, so this combination is not recommended.

Patient with hepatic impairment: No dosage adjustment is necessary with hepatic impairment.

Contraindication

This combination is contraindicated in patients with known hypersensitivity to Olmesartan or hydrochlorothiazide or any components of this product. It is also contraindicated in patients with anuria.

Warning and precaution

All patients receiving thiazide therapy should be observed for clinical signs of fluid or electrolyte imbalance: Hyponatremia, Hypochloremic alkalosis and Hypokalemia. Hypokalemia may develop, especially with rapid diuresis, when severe cirrhosis is present or after prolonged therapy. As a consequence of inhibiting the renin-angiotensin-aldosterone system, changes in renal function may be anticipated in susceptible individuals treated with Olmesartan.

Side effect

The common side effects are nausea, headache, dizziness, hyperuricemia upper respiratory tract infection and urinary tract infection. Other side effects are chest pain, back pain, peripheral edema, abdominal pain, dyspepsia, gastroenteritis and diarrhea.

Use in pregnancy and lactation

This combination is pregnancy categories C in first trimester and D in second and third trimesters. The use of this combination is not recommended during the first trimester of pregnancy. The use of this combination is contraindicated during the second and third trimester of pregnancy. It is not known whether Olmesartan medoxomil is excreted in human milk, but Olmesartan medoxomil is secreted at low concentration in the milk of lactating rats. Thiazides appear in human milk. Because of the potential for adverse effects on the nursing infant, a decision should be made whether to discontinue nursing or discontinue the drug, taking into account the importance of the drug to the mother.

Use in children and adolescents

This combination is not recommended for use in children below 18 years due to a lack of data on safety and efficacy.

Drug interaction

Drugs that interact with Olmesartan medoxomil: No significant drug interactions were reported in which Olmesartan medoxomil was co-administered with hydrochlorothiazide, digoxin or warfarin in healthy volunteers.

Drugs that interact with Hydrochlorothiazide: When administered concurrently the following drugs may interact with thiazide diuretics such as alcohol, barbiturates or narcotics, antidiabetic drugs, other antihypertensive drugs, cholestyramine and colestipol resins, corticosteroids, pressor amines (e.g. Norepinephrine), skeletal muscle relaxants (e.g. Tubocurarine), lithium and NSAIDs.

Overdose

Limited data are available in regard to overdose of Olmesartan medoxomil in humans. The most likely manifestation of overdose would be hypotension and tachycardia. Supportive treatment should be instituted. The most common signs and symptoms of hydrochlorothiazide overdose observed are those caused by electrolyte depletion (hypokalemia, hypochloremia and dehydration) resulting from excessive diuresis. If digitalis has also been administered hypokalemia may accentuate cardiac arrhythmias.

Storage

Do not store above 25^0 C. Protect from light. Keep out of reach of children.

Packing

Olpres HZ 20/12.5 Tablet: Each box contains 3×10's tablets in blister pack.

Olpres HZ 40/12.5 Tablet: Each box contains 3×10's tablets in blister pack.

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Manufactured by

ZISKA PHARMA

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Kaliakoir, Gazipur, Bangladesh

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