

Olsart-HZ®

Olmesartan medoxomil & hydrochlorothiazide

Description

Olmesartan + Hydrochlorothiazide is a combination of an angiotensin II receptor antagonist (AT1 subtype), olmesartan medoxomil, and a thiazide diuretic, hydrochlorothiazide (HCTZ). Olmesartan medoxomil, a prodrug, is hydrolyzed to olmesartan during absorption from the gastrointestinal tract.

Mode of action

Olmesartan blocks the vasoconstrictor effects of angiotensin II by selectively blocking the binding of angiotensin II to the AT1 receptor in vascular smooth muscle. Its action is, therefore, independent of the pathways for angiotensin II synthesis.

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. Co-administration of an angiotensin II receptor antagonist tends to reverse the potassium loss associated with these diuretics. The mechanism of the antihypertensive effect of thiazides is not fully understood.

Pharmacokinetics

Olmesartan medoxomil is rapidly and completely bioactivated by ester hydrolysis to olmesartan during absorption from the gastrointestinal tract. Olmesartan shows linear pharmacokinetics following single oral doses of up to 320 mg and multiple oral doses of up to 80 mg. Steady-state levels of olmesartan are achieved within 3 to 5 days and no accumulation in plasma occurs with once-daily dosing.

The absolute bioavailability of olmesartan is approximately 26%. After oral administration, the peak plasma concentration (C_{max}) of olmesartan is reached after 1 to 2 hours. Food does not affect the bioavailability of olmesartan.

Hydrochlorothiazide: The plasma half-life has been observed to vary between 5.6 and 14.8 hours.

After oral administration of hydrochlorothiazide, diuresis begins within 2 hours, peaks in about 4 hours and lasts about 6 to 12 hours.

Composition

Olsart-HZ® 20 Tablet: Each film coated tablet contains Hydrochlorothiazide BP 12.5 mg & Olmesartan Medoxomil INN 20 mg.

Olsart-HZ® 40 Tablet: Each film coated tablet contains Hydrochlorothiazide BP 12.5 mg & Olmesartan Medoxomil INN 40 mg.

Indications

Olsart-HZ® 20 Tablet: It is indicated for the treatment of stage-II hypertension.

Olsart-HZ® 40 Tablet: It is indicated for the treatment of uncontrolled stage-II hypertension. Fixed dose combination is not indicated for initial therapy.

Dosage & administration

The usual recommended starting dose of olmesartan medoxomil is 20 mg once daily when used as monotherapy. For patients requiring further reduction in blood pressure after 2 weeks of therapy, the dose may be increased to 40 mg.

Hydrochlorothiazide is effective in doses between 12.5 mg and 50 mg once daily.

Contraindications

It 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.

Side effects

Patient may experience dizziness, lightheadedness, blurred vision, unusual thirst, muscle cramps, weakness, confusion, fast/irregular heartbeat, fainting, seizures, decreased sexual ability.

Use in pregnancy & lactation

Pregnancy Categories C.

It is not known whether olmesartan is excreted 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.

Precautions

All patients receiving thiazide therapy should be observed for clinical signs of fluid or electrolyte imbalance: hyponatremia, hypochloremic alkalosis and hypokalemia. Serum and urine electrolyte determinations are important when the patient is vomiting excessively or receiving parenteral fluids. Warning signs or symptoms of fluid and electrolyte imbalance, irrespective of cause, include dryness of mouth, thirst, weakness, lethargy, drowsiness, restlessness, confusion, seizures, muscle pains or cramps, muscular fatigue, hypotension, oliguria, tachycardia and gastrointestinal disturbances such as nausea and vomiting. Hypokalemia may develop, especially with brisk diuresis, when severe cirrhosis is present, or after prolonged therapy.

Drug interactions

Cisapride, corticosteroids, diazoxide, digoxin, drugs which can increase dizziness (e.g., phenobarbital, narcotic analgesics), drugs which are affected by the acid level in the urine (e.g., amphetamine, methenamine, quinidine), lithium, probenecid.

Over dosage

Limited data are available related to overdosage in humans. The most likely manifestations of overdosage would be hypotension and tachycardia; bradycardia could be encountered if parasympathetic (vagal) stimulation occurs.

Storage

Store in a cool and dry place, protected from light.

Packaging

Olsart-HZ® 20 Tablet: Each carton contains 10X3 tablets in blister pack.

Olsart-HZ® 40 Tablet: Each carton contains 10X3 tablets in blister pack.



Manufactured by
Opsonin Pharma Limited
Rupatali, Barishal, Bangladesh.
® Registered Trade Mark.