Olsart® Plus

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. It's 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 increase excretion of sodium and chloride in approximately equivalent amounts. Co-administration of an angiotensin II receptor antagonist tend 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® Plus 20 Tablet: Each film coated tablet contains Olmesartan Medoxomil BP 20 mg & Hydrochlorothiazide BP 12.5 mg.
Olsart® Plus 40 Tablet: Each film coated tablet contains Olmesartan Medoxomil BP 40 mg & Hydrochlorothiazide BP 12.5 mg.

Indications
Olsart® Plus 20 Tablet: It is indicated for the treatment of stage-II hypertension.
Olsart® Plus 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 components 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 Category 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 or not 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 electrolytes determination 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
Keep out of reach of children. Store in a dry place, below 25˚C temperature and protected from light.

Packaging
Olsart® Plus 20 Tablet: Each carton contains 14X3 tablets in blister pack.
Olsart® Plus 40 Tablet: Each carton contains 14X3 tablets in blister pack.

Opsonin Pharma
Ideas for healthcare

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