Olmetor® Plus

Olmesartan Medoxomil USP + Hydrochlorothiazide USP

COMPOSITION

Olmetor® Plus 20 tablet: Each film coated tablet contains Olmesartan Medoxomil USP 20 mg and Hydrochlorothiazide USP 12.5 mg.
Olmetor® Plus 40 tablet: Each film coated tablet contains Olmesartan Medoxomil USP 40 mg and Hydrochlorothiazide USP 12.5 mg.

PHARMACOLOGY

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. Olmesartan blocks 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 Olmesartan is a reversible & competitive inhibitor of AT1 receptor. Olmesartan does not inhibit ACE (kinase-I, the enzyme that converts angiotensin-I to angiotensin- II and degrades bradykinin).

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 Aldosterone secretion & urinary Potassium loss and decreases 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.

INDICATION

Olmetor® Plus is indicated for the treatment of hypertension.

DOSAGE & ADMINISTRATION

Hypertension-
The usual starting dose of **Olmetor® Plus** is 20/12.5 mg one tablet once daily. Dosing should be individualized. Depending on the blood pressure response, the dose may be titrated at intervals of 2-4 weeks.
Patients with Renal Impairment-
The usual regimens of therapy with **Olmetor® Plus** 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, **Olmetor® Plus** is not recommended. *Patients with Hepatic Impairment*-No dosage adjustment is necessary with hepatic impairment.

CONTRAINDICATION

The combination of Olmesartan 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.

SIDE EFFECTS

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

PRECAUTIONS AND WARNING

• Periodic determination of serum electrolytes should be performed at appropriate intervals to detect possible electrolyte imbalance like hypokalemia, hyponatremia and hypochloremic alkalosis
• Hyperuricemia may occur in certain patients receiving thiazide therapy
• Impaired renal function

USE IN PREGNANCY AND LACTATION

Safety and effectiveness in nursing mother & pregnancy have not been established. The drug should be discontinued during these conditions.

Paediatric use:
Safety and effectiveness in paediatric patients have not been established.

Geriatric use:
Clinical studies of Olmesartan and Hydrochlorothiazide combination did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects. In general, dose selection for an elderly patient should be cautious.

DRUG INTERACTION

Olmesartan-
No significant drug interactions were reported in studies in which Olmesartan Medoxomil was co-administered with hydrochlorothiazide, digoxin or warfarin in healthy volunteers. Olmesartan Medoxomil is not metabolized by the cytochrome P450 system and has no effects on P450 enzymes; thus, interactions with drugs that inhibit, induce or are metabolized by those enzymes are not expected.
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
• Corticosteroids, ACTH
• Lithium

OVERDOSE

Olmesartan-
Limited data are available in regard to over dosage in humans. The most likely manifestation of over dosage would be hypotension and tachycardia. Supportive treatment should be instituted.
Hydrochlorothiazide-
The most common signs and symptoms 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

Store at temperature not exceeding 30°C in a dry place.
Protect from light & moisture. Keep out of reach of children.

COMMERCIAL PACK

Olmetor® Plus 20 tablet: Each box contains 3 x 10's tablet in Alu-Alu blister pack.
Olmetor® Plus 40 tablet: Each box contains 3 x 10's tablet in Alu-Alu blister pack.

EURO
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