OLMETAB

OLMESARTAN MEDOXOMIL USP

Compositions:
Olmetab-10 Tablet: Each tablet contains Olmesartan Medoxomil USP 10 mg. Olmetab-20 Tablet: Each tablet contains Olmesartan Medoxomil USP 20 mg. Olmetab-40 Tablet: Each tablet contains Olmesartan Medoxomil USP 40 mg.

Pharmacology:
Olmesartan Medoxomil, a prodrug, is hydrolyzed to Olmesartan during absorption from the gastrointestinal tract. Olmesartan is a selective angiotensin II receptor (AT1 subtype) antagonist. It blocks the actions of angiotensin II mediated by the AT1 receptor, regardless of the source or route of synthesis of angiotensin II.

Dosage And Administration:
Dosage & Administration: Adult: Dosage must be individualized. The usual recommended starting dose of Olmesartan Medoxomil is 20 mg once daily when used as monotherapy in patients who are not volume-contracted. For patients requiring further reduction in blood pressure after 2 weeks of therapy, the dose may be increased to 40 mg. Doses above 40 mg do not appear to have greater effect. Twice daily dosing offers no advantage over the same total dose given once daily. No initial dosage adjustment is recommended for elderly patients, for patients with moderate to marked renal impairment (creatinine clearance < 40 ml/min) or with moderate to marked hepatic dysfunction. For patients with possible depletion of intravascular volume (e.g.; patients treated with diuretics, particularly those with impaired renal function), Olmesartan should be initiated under close medical supervision and consideration should be given to use of a lower starting dose. Olmesartan may be administered with or without food. Children (6–16 years of age): Children weight between 20 kg to less than 35 kg: Usual starting dose is 10 mg once daily. If the blood pressure is not well controlled, your doctors can double the dosage to 20 mg once daily. Children weight 35 kg or more: Usual starting dose is 20 mg once daily. If the blood pressure is not well controlled, your doctors can double the dosage to 40 mg once daily.

Contraindications:
Olmesartan is contraindicated in patients who are hypersensitive to any component of this product.

Warning And Precaution:
As a consequence of inhibiting the renin-angiotensin-aldosterone system, changes in renal function may be anticipated in susceptible individuals treated with Olmesartan. In patients whose renal function may depend upon the activity of the renin-angiotensin-aldosterone system (e.g. patients with severe congestive heart failure), treatment with angiotensin converting enzyme inhibitors and angiotensin receptor antagonists has been associated with oliguria and/or progressive azotemia and (rarely) with acute renal failure and/or death. Similar results may be anticipated in patients treated with Olmesartan.

Side Effects:
Treatment with Olmesartan is well tolerated, with an incidence of adverse events similar to placebo. The following adverse events occurred in placebo controlled clinical trials at an incidence of more than 1% of patients treated with Olmesartan, but also occurred at about the same or greater incidence in patients receiving placebo: back pain, bronchitis, increased creatine phosphokinase, diarrhea, headache, hematuria, hyperglycemia, hypertriglyceridemia, influenza like symptoms, pharyngitis, rhinitis and sinusitis.

Use in Pregnancy and Lactation:
Pregnancy category C (first trimester) and D (second and third trimesters). Olmesartan should not be used during pregnancy. When pregnancy is detected, it should be discontinued as soon as possible.It is not known whether Olmesartan is excreted in human milk, but Olmesartan is secreted at low concentration in the milk of lactating rats. 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.

Drug Interaction:
No significant drug interactions were reported when Olmesartan was co-administered with digoxin or warfarin. The blood pressure lowering effect of Olmesartan Medoximil can be increased by concomitant use of other antihypertensive medications. Use of potassium-sparing diuretics, potassium supplements, and salt substitutes containing potassium or other drugs that may increase serum potassium levels (e.g. heparin) may lead to increases in serum potassium, such concomitant use is therefore not recommended. In patients who are elderly, volume-depleted (including those on diuretic therapy), or with compromised renal function, co-administration of NSAIDs, including selective COX-2 inhibitors, with angiotensin II receptor antagonists, including Olmesartan, may result in deterioration of renal function, including possible acute renal failure.

Overdosage:
In case of drug overdose, contact a health care practitioner or hospital emergency department.

Storage:
Store in a cool (below 25°C) and dry place, protect from light and moisture. Keep out of the reach of children.

Packing:
Olmetab-10 Tablet: Each box contains 5 x 10's tablet in Alu-Alu blister pack. Olmetab-20 Tablet: Each box contains 5 x 10's tablet in Alu-Alu blister pack. Olmetab-40 Tablet: Each box contains 5 x 10's tablet in Alu-Alu blister pack.

Manufactured By:
The IBN SINA Pharmaceutical Industry PLC.
Shafipur, Gazipur, Bangladesh.