Olmecar™

Olmesartan Medoxomil

Angiotensin II Receptor Blocker

PRESENTATION

Olmecar™ 20 tablet: Each film coated tablet contains Olmesartan Medoxomil INN 20 mg.

Olmecar™ 40 tablet: Each film coated tablet contains Olmesartan Medoxomil INN 40 mg.

DESCRIPTION

Olmesartan medoxomil is a selective angiotensin II receptor antagonist (AT_1 subtype). Olmesartan medoxomil a prodrug, is hydrolyzed to olmesartan during absorption from the gastrointestinal tract.

USES

For the treatment of hypertension. It may be used alone or in combination with other antihypertensive agents.

DOSAGE & ADMINISTRATION

Dosage must be individualized. The usual recommended starting dose of Olmesartan 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 of Olmesartan 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.

CONTRAINDICATION

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

SIDE EFFECTS

Treatment with Olmesartan was 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, creatine phosphokinase increased,

diarrhea, headache, hematuria, hyperglycemia, hypertriglyceridemia, influenza-like symptoms, pharyngitis, rhinitis and sinusitis.

USE IN PREGNANCY AND LACTATION

Pregnancy Categories: C (first trimester) and D (second and third trimesters).

Nursing Mothers:

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.

PAEDIATRIC USE

Safety and effectiveness in pediatric patients have not been established.

PRECAUTION

As a consequence of inhibiting the renin-angiotensin-aldosterone system, changes in renal function may be anticipated in susceptible individuals treated with olmesartan medoxomil. 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 medoxomil.

STORAGE CONDITION

Store in a cool and dry place, protect from light and moisture. Keep out of the reach of children.

HOW SUPPLIED

Olmecar™ **20** tablet: Each box contains 30 tablets in blister pack.
Olmecar™ **40** tablet: Each box contains 30 tablets in blister pack.

Manufactured by:

SQUARE
PHARMACEUTICALS LTD.
BANGLADESH

TM - Trade Mark