Olmecar™ Plus

Olmesartan Medoxomil 20 mg + Hydrochlorothiazide 12.5 mg tablet

PRESENTATION

Olmecar™ Plus 20/12.5 tablet: Each film coated tablet contains Olmesartan Medoxomil INN 20 mg & Hydrochlorothiazide BP 12.5 mg.

INDICATIONS & USES

Indicated for the treatment of hypertension. This 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 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. 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. Hydrochlorothiazide is effective in doses between 12.5 mg and 50 mg once daily. Replacement Therapy: **Olmecar**™ Plus may be substituted for its titrated components. Dose Titration by Clinical Effect: The dose of **Olmecar**™ Plus tablet is one tablet once daily. More than one tablet daily is not recommended. Olmecar™ Plus tablet may be administered with other antihypertensive agents. A patient whose blood pressure is inadequately controlled by Olmesartan or Hydrochlorothiazide alone may be switched to once daily **Olmecar**™ Plus tablet. Dosing should be individualized. Depending on the blood pressure response, the dose may be titrated at intervals of 2-4 weeks. If blood pressure is not controlled by Olmesartan alone, Hydrochlorothiazide may be added starting with a dose of 12.5 mg and later titrated to 25 mg once daily. If a patient is taking Hydrochlorothiazide, Olmesartan may be added starting with a dose of 20 mg once daily and titrated to 40 mg, for inadequate blood pressure control. If large doses of Hydrochlorothiazide have been used as monotherapy and volume depletion or hyponatremia is present, caution should be used when adding Olmesartan or switching to **Olmecar**™ Plus tablet, as marked decreases in blood pressure may occur. Consideration should be given to reducing the dose of Hydrochlorothiazide to 12.5 mg before adding Olmesartan. The antihypertensive effect of **Olmecar**™ Plus tablet is related to the dose of both components over the range of 10 mg/12.5 mg to 40 mg/25 mg. Patients with Renal Impairment: The usual regimens of therapy with **Olmecar**™ Plus tablet may be followed provided the patient's creatinine clearance>30 ml/min. In patients with more severe renal impairment, loop diuretics are preferred to thiazides, so this combination tablet is not recommended. Patients with Hepatic Impairment: No dosage adjustment is necessary with hepatic impairment.

USE IN PREGNANCY AND LACTATION

Pregnancy: Pregnancy Categories C (first trimester) and D (second and third trimesters). This combination drug should not be used during pregnancy. 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. Thiazides appear 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.

USE IN CHILDREN

Safety and effectiveness in pediatric patients have not been established.

HOW SUPPLIED:

Olmecar™ Plus 20/12.5 tablet: Each box contains 30 tablets in blister pack.

Manufactured by

SQUARE
PHARMACEUTICALS LTD.
BANGLADESH