Olmecar™ Plus

Olmesartan Medoxomil + Hydrochlorothiazide

Angiotensin II Receptor Blocker+Thiazide Diuretic

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.

CONTRAINDICATION

This combination tablet 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

This combination tablet has been evaluated for safety in 1,243 hypertensive patients. It was well tolerated, with an incidence of adverse events similar to placebo. Events generally were mild, transient and had no relationship to the dose of this combination tablet. Some common side effects include: headache, urinary tract infection, chest pain, back pain, peripheral edema,

vertigo, abdominal pain, dyspepsia, gastroenteritis, diarrhoea, SGOT increased, GGT increased, SGPT increased, hyperlipemia, creatine phosphokinase increased, hyperglycemia, arthritis, arthralgia, myalgia, coughing, rash etc.

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.

DRUG INTERACTION

Olmesartan Medoxomil

No significant drug interactions were reported in studies in which Olmesartan Medoxomil was co-administered with hydrochlorothiazide, digoxin or warfarin in healthy volunteers.

Hydrochlorothiazide

When administered concurrently the following drugs may interact with thiazide diuretics: alcohol, barbiturates or narcotics, antidiabetic drugs, other antihypertensive drugs, cholestyramine and colestipol resins, corticosteroids, pressor amines (e.g. Norepinephrine), skeletal muscle relaxants (e.g. Tubocurarine), lithium, NSAIDs etc.

OVERDOSAGE

Olmesartan Medoxomil

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.

Hydrochlorothiazide

The most common signs and symptoms of overdose observed in humans are those caused by electrolyte depletion (hypokalemia, hypochloremia, hyponatremia) and dehydration resulting from excessive diuresis.

STORAGE CONDITION

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

HOW SUPPLIED

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

Manufactured by:

SQUARE

PHARMACEUTICALS LTD.

BANGLADESH