Olmecar™ Plus 20/12.5

Olmesartan Medoxomil & Hydrochlorothiazide

PRESENTATION

Olmecar™ Plus 20/12.5 tablet: Each film coated tablet contains Olmesartan Medoxomil Ph. Eur. 20 mg and Hydrochlorothiazide Ph. Eur. 12.5 mg.

INDICATIONS & USES

Indicated for the treatment of hypertension. This fixed dose combination is not indicated for initial therapy.

DOSAGE & ADMINISTRATION

The recommended dose is one **Olmecar**™ Plus 20/12.5 tablet a day. However, if the blood pressure is not controlled, then, as per the doctor's recommendation, the dose can be increased. Swallow the tablet with water at the same time each day. It is important to continue taking **Olmecar**™ Plus 20/12.5 tablet until the doctor tells you to stop.

Patients with Renal Impairment: The usual regimens of therapy with **Olmecar**™ Plus 20/12.5 tablet may be followed provided the patient's creatinine dearance>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.

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

It was well tolerated, with an incidence of adverse events similar to placebo. 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.

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, norepinephrine, tubocurarine, lithium, NSAIDs etc.

USE IN CHILDREN

Safety and effectiveness in pediatric patients have not been established.

OVERDOSAGE

Olmesartan Medoxomil: Limited data are available related to overdosage in humans. The most likely manifestations of overdosage would be hypotension and tachycardia. *Hydrochlorothiazide:* The most common signs and symptoms of overdose observed in humans are hypokalemia, hypochloremia, hyponatremia and dehydration.

STORAGE CONDITION

Store below 30° C, in a dry place. Keep all medicines out of reach of children.

HOW SUPPLIED

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

Manufactured by-

SQUARE LIFESCIENCES LTD.