Olmetic
Tablet

DRUG INTERNATIONAL LTD.

Composition : **Olmetic :** Each film coated tablet contains Olmesartan Medoxomil BP 20mg.

Pharmacology : Hydrochlorothiazide inhibits the reabsorption of Na in the distal tubules causing increased excretion of Na and water including K and hydrogen ions. Olmesartan is an angiotensin II receptor blocker that acts on AT1 subtype. By blocking the action of angiotensin II, Olmesartan dilates blood vessels and reduces blood pressure without affecting pulse rate.

Indications : Olmesartan Medoxomil is indicated for the treatment of hypertension. It may be used alone or in combination with other antihypertensive agents.

Dosage and administration : **Olmetic : Adults:** Dosage must be individualized. The usual recommended starting dose of Olmesartan Medoxomil is 10 to 20mg once daily when used as monotherapy. For patients requiring further reduction in blood pressure after 2 weeks of therapy, the dose of Olmesartan Medoxomil may be increased to 20 to 40 mg. Maximum recommended daily dose is 40mg. **Elderly and renal impairment:** The maximum dose in elderly and patients with mild to moderate renal impairment is 20mg daily. **Children and adolescents:** The safety and efficacy have not been established in children and adolescents up to 18 years of age. **Olmetic Plus :** A patient whose blood pressure is inadequately controlled by olmesartan or hydrochlorothiazide alone may be switched to one tablet (olmesaran medoxomil 20mg-hydrochlorothiazide 12.5mg) once daily. Patients with Renal Impairment : The usual regimens of therapy with olmesartan-hydrochlorothiazide may be followed provided the patient's creatinine clearance is >30 mL/min. In patients with more severe renal impairment, loop diuretics are preferred to thiazides, so olmesartan-hydrochlorothiazide is not recommended. Patients with Hepatic Impairment: No dosage adjustment is necessary with hepatic impairment. Or, as directed by the registered physicians.

Contraindication : This tablet is contraindicated in patients who are hypersensitive to any components of this product. Because of the hydrochlorothiazide component, the combination product is contraindicated in patients with anuria or hypersensitivity to other sulfonamide-derived drugs.

Precautions : Angiotensin II receptor antagonist should be used with caution in patients with severe renal impairment (creatinine clearance<20ml/min) and patients with sever congestive heart failure. Due to limited experience, the use of Olmesartan Medoxomil is not recommended in patients with hepatic impairment. All patients receiving thiazide therapy should be observed for clinical signs of fluid or electrolyte imbalance: hyponatremia, hypochloremic alkalosis and hypokalemia. Serum and urine electrolyte determinations are important when the patient is vomiting excessively or receiving parenteral fluids. Warning signs or symptoms of fluid and electrolyte imbalance, irrespective of cause, include dryness of mouth, thirst, weakness, lethargy, drowsiness, restlessness, confusion, seizures, muscle pains or cramps, muscular fatigue, hypotension, oliguria, tachycardia and gastrointestinal disturbances such as nausea and vomiting. Hypokalemia may develop especially with brisk diuresis, when severe cirrhosis is present or after prolonged therapy.

Side effects : The most frequent side effects related to olmesartan are 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, hematuria. The most frequent side effects related to Hydrochlorothiazide are weakness, pancreatitis, jaundice, gastric irritation, aplastic anemia, leukopenia, thrombocytopenia, purpura, photosensitivity, urticaria, muscle spasm, restlessness, renal failure.

Use in pregnancy and lactation : Pregnancy Categories C (first trimester) and D (second and third trimesters). It is not known whether Olmesartan Medoxomil is excreted in human milk. Mothers must not breast-feed if they are taking Olmesartan Medoxomil. Drugs that act directly on the renin-angiotensin system can cause fetal and neonatal morbidity and death when administered to pregnant women. When pregnancy is detected, this drug should be discontinued as soon as possible. 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 Child : No data are available.

Drug Interactions : Olmesartan medoxomill: No significant drug interactions were reported in studies in which Olmesartan 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. Dosage adjustment of the antidiabetic drug may be required. Other antihypertensive drugs-additive effect or potentiation.

Overdose : Olmesartan medoxomil: The most likely manifestations of overdosage would be hypotension and tachycardia, bradycardia could be encountered if parasympathetic 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 : Store below 30°C in a dry place.

Packing : **Olmetic :** Each box contains 3 x 14's tablets in blister pack.