

OLMETOR-H

For the use of a Registered Medical Practitioner or a Hospital or a Laboratory Only

Abbreviated Prescribing information for OLMETOR-H [Olmesartan Medoxomil 20 mg & Hydrochlorothiazide 12.5 mg Tablets I.P]

[Please refer the complete prescribing information available at www.torrentpharma.com]

PHARMACOLOGICAL PROPERTIES:

MECHANISM OF ACTION: *Olmesartan medoxomil* Angiotensin II is formed from angiotensin I in a reaction catalyzed by angiotensin converting enzyme (ACE, kininase II). Angiotensin II is the principal pressor agent of the renin-angiotensin system, with effects that include vasoconstriction, stimulation of synthesis and release of aldosterone, cardiac stimulation and renal reabsorption of sodium. Olmesartan blocks the vasoconstrictor effects of angiotensin II by selectively blocking the binding of angiotensin II to the AT1 receptor in vascular smooth muscle. Its action is, therefore, independent of the pathways for angiotensin II synthesis. An AT receptor is found also in many tissues, but this receptor is not known to be associated with cardiovascular homeostasis. Olmesartan has more than a 12,500-fold greater affinity for the AT receptor than for the AT receptor. Blockade of the angiotensin II receptor inhibits the negative regulatory feedback of angiotensin II on renin secretion, but the resulting increased plasma renin activity and circulating angiotensin II levels do not overcome the effect of olmesartan on blood pressure.

Hydrochlorothiazide Hydrochlorothiazide is a thiazide diuretic. Thiazides affect the renal tubular mechanisms of electrolyte reabsorption, directly increasing excretion of sodium and chloride in approximately equivalent amounts. Indirectly, the diuretic action of hydrochlorothiazide reduces plasma volume, with consequent increases in plasma renin activity, increases in aldosterone secretion, increases in urinary potassium loss, and decreases in serum potassium. The renin-aldosterone link is mediated by angiotensin II, so co-administration of an angiotensin II receptor antagonist tends to reverse the potassium loss associated with these diuretics. The mechanism of the antihypertensive effect of thiazides is not fully understood

INDICATIONS: Ometor-H is indicated for the treatment of mild to moderate hypertension in adults (Not indicated for initial therapy.)

DOSAGE AND ADMINISTRATION: The recommended starting dose of Olmesartan medoxomil and hydrochlorothiazide tablet is 40/12.5 mg once daily in patients whose blood pressure is not adequately controlled with Olmesartan monotherapy. Dose can be titrated up to 40 /25 mg if necessary. The recommended starting dose of Olmesartan medoxomil and hydrochlorothiazide tablet is 20/12.5 mg once daily in patients whose blood pressure is not adequately controlled with HCT monotherapy or who experience dose-limiting adverse reactions with hydrochlorothiazide. Dose can be titrated up to 40 /25 mg if necessary. Patients titrated to the individual components (Olmesartan and hydrochlorothiazide) may instead receive the corresponding dose of Olmesartan medoxomil and hydrochlorothiazide tablet

CONTRAINDICATION: In patients with hypersensitivity to any component of olmesartan medoxomil and hydrochlorothiazide tablet In patients with anuria For coadministration with aliskiren in patients with diabetes.

WARNINGS & PRECAUTIONS: Fetal toxicity, hypotension in volume or salt depleted patients, impaired renal function, hypersensitivity reactions, electrolyte and metabolic imbalances, acute myopia and secondary angle-closure glaucoma, systemic lupus erythematosus, sprue-like enteropathy.

DRUG INTERACTIONS: Coadministration of olmesartan medoxomil and hydrochlorothiazide tablet with other drugs that raise serum potassium levels may result in hyperkalemia. Monitor serum potassium in such patients. Concurrent administration of bile acid sequestering agent colesevelam hydrochloride reduces the systemic exposure and peak plasma concentration of olmesartan. Administration of olmesartan at least 4 hours prior to colesevelam hydrochloride decreased the drug interaction effect.

Consider administering olmesartan at least 4 hours before the colesevelam hydrochloride dose. Antidiabetic drugs (oral agents and insulin): Dosage adjustment of the antidiabetic drug may be required. Ion exchange resins: Staggering the dosage of hydrochlorothiazide and ion exchange resins (e.g., cholestyramine, colestipol) such that hydrochlorothiazide is administered at least 4 hours before or 4 – 6 hours after the administration of resins would potentially minimize the interaction.

ADVERSE REACTIONS: Nausea, hyperuricemia, dizziness, upper respiratory infection, chest pain, back pain, peripheral edema, vertigo, abdominal pain, dyspepsia, gastroenteritis, diarrhea, SGOT increased, GGT increased, ALT increased, creatine phosphokinase increased, arthritis, arthralgia, myalgia, coughing rash. anaemia, agranulocytosis, leukopenia, haemolytic anaemia, thrombocytopenia Hypersensitivity: purpura, photosensitivity, urticaria, necrotizing angiitis (vasculitis and cutaneous vasculitis), fever, respiratory distress including pneumonitis and pulmonary edema, anaphylactic reactions pancreatitis, jaundice (intrahepatic cholestatic jaundice), sialadenitis, cramping, gastric irritation Alopecia, pruritus.

MARKETED BY:

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(Additional information is available on request)