OLMETOR H

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

Abbreviated Prescribing information for OLMETOR H (Olmesartan Medoxomil 20,40mg and Hydrochlorothiazide 12.5mg tablets)[Please refer the complete prescribing information available at www.torrentpharma.com

PHARMACOLOGICAL PROPERTIES: - Olmesartan blocks the vasoconstrictor effects of angiotensin II by selectively blocking the binding of angiotensin II to the AT_1 receptor in vascular smooth muscle. Hydrochlorothiazide is a thiazide diuretic, 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.

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

DOSAGE AND ADMINISTRATION: A patient whose blood pressure is inadequately controlled by Olmesartan or hydrochlorothiazide alone may be switched to once daily Olmetor-H 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.

CONTRAINDICATION: Hypersensitivity to the active substances, to any of the excipients or to other sulfonamide derived substances, severe renal impairment, refractory hypokalaemia, hypercalcaemia, hyponatraemia, symptomatic hyperuricaemia, severe hepatic impairment, cholestasis , biliary obstructive disorders. And second and third trimester of pregnancy

WARNINGS & PRECAUTIONS: Fetal toxicity use of drugs that act on the renin-angiotensin system during the second and third trimesters of pregnancy reduces fetal renal function and increases fetal and neonatal morbidity and death. in patients with an activated renin-angiotensin aldosterone system, such as volume- and/or salt-depleted patients (e.g., those being treated with high doses of diuretics), symptomatic hypotension may be anticipated after initiation of treatment with olmesartan. impaired renal function, sprue-like enteropathy severe, chronic diarrhea with substantial weight loss has been reported in patients taking olmesartan months to years after drug initiation, hepatic impairment, hypersensitivity reaction, systemic lupus erythematosus, lithium interaction, acute myopia and secondary angle-closure glaucoma.

DRUG INTERACTIONS: NSAIDS, colesevelam hydrochloride and Lithium.

Hydrochlorothiazide Alcohol, Barbiturates, Or Narcotics – potentiation of orthostatic hypotension may occur. Antidiabetic Drugs (oral agents and insulin) – dosage adjustment of the antidiabetic drug may be required. Other Antihypertensive Drugs – additive effect or potentiation. Cholestyramine and Colestipol Resins, Corticosteroids, ACTH and Pressor Amines.

ADVERSE REACTIONS: Nausea, hyperuricemia , dizziness , upper respiratory tract infection chest pain, peripheral edema, vertigo , SGOT, GGT and SGPT increased, hematuria facial edema, tachycardia , abdominal pain, dyspepsia, gastroenteritis, nausea , tachycardia , hypercholesterolemia, hyperlipemia, hyperuricemia, elevations of liver enzymes and/or serum bilirubin were observed infrequently, adult hypertension **,** asthenia, dizziness, flushing, palpitation, somnolence, angioedema, anaphylactic reactions, ***Hydrochlorothiazide*** - pancreatitis, jaundice, sialadenitis, cramping, gastric irritation, aplastic anemia, agranulocytosis, leukopenia, hemolytic anemia, thrombocytopenia, purpura, photosensitivity, urticaria, necrotizing angiitis, fever, respiratory distress including pneumonitis and pulmonary edema, anaphylactic reactions, renal failure, renal dysfunction, interstitial nephritis erythema multiforme including stevens-johnson syndrome, exfoliative dermatitis including toxic epidermal necrolysistransient blurred vision, xanthopsia,vomiting, diarrhea, , rhabdomyolysis, alopecia, pruritus, urticaria, gynecomastia, jaundice and hepatic enzyme elevations.

MARKETED BY:

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(Additional information is available on request)