OLSAR

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

Abbreviated Prescribing information for OLSAR

(Olmesartan Medoxomil Tablets I.P.) [Please refer the complete prescribing information for details].

PHARMACOLOGICAL PROPERTIES:

Mechanism of Action: Olmesartan medoxomil is a potent, orally active, selective angiotensin II receptor (type AT1) antagonist. It is expected to block all actions of angiotensin II mediated by the AT1 receptor, regardless of the source or route of synthesis of angiotensin II. The selective antagonism of the angiotensin II (AT1) receptors results in increases in plasma renin levels and angiotensin I and II concentrations, and some decrease in plasma aldosterone concentrations.

Angiotensin II is the primary vasoactive hormone of the renin-angiotensin-aldosterone system and plays a significant role in the pathophysiology of hypertension via the type 1 (AT1) receptor.

INDICATIONS: Anti-hypertensive

DOSAGE AND ADMINISTRATION: As directed by the Physician

CONTRAINDICATION: Hypersensitivity to the active substance or to any of the excipients. Second and third trimesters of pregnancy. Biliary obstruction**:** The concomitant use of Olmesartan Tablets with aliskiren-containing products is contraindicated in patients with diabetes mellitus or renal impairment (GFR < 60 ml/min/1.73 m2)

WARNINGS & PRECAUTIONS: Intravascular volume depletion Symptomatic hypotension, especially after the first dose, may occur in patients who are volume and/or sodium depleted by vigorous diuretic therapy, dietary salt restriction, and diarrhoea or vomiting. Such conditions should be corrected before the administration of Olmesartan Medoxomil. Other conditions with stimulation of the renin-angiotensin-aldosterone system In patients whose vascular tone and renal function depend predominantly on the activity of the renin-angiotensin-aldosterone system (e.g. patients with severe congestive heart failure or underlying renal disease, including renal artery stenosis), treatment with other drugs that affect this system has been associated with acute hypotension, azotaemia, oliguria or, rarely, acute renal failure. The possibility of similar effects cannot be excluded with angiotensin II receptor antagonists. Renovascular hypertension There is an increased risk of severe hypotension and renal insufficiency when patients with bilateral renal artery stenosis or stenosis of the artery to a single functioning kidney are treated with medicinal products that affect the renin-angiotensin-aldosterone system. Renal impairment and kidney transplantation When Olmesartan Medoxomil is used in patients with impaired renal function, periodic monitoring of serum potassium and creatinine levels is recommended. Use of olmesartan medoxomil is not recommended in patients with severe renal impairment (creatinine clearance < 20 ml/min). There is no experience of the administration of olmesartan medoxomil in patients with a recent kidney transplant or in patients with end-stage renal impairment (i.e. creatinine clearance < 12 ml/min). Hepatic impairment There is no experience in patients with severe hepatic impairment and therefore use of olmesartan medoxomil in this patient group is not recommended. Hyperkalaemia The use of medicinal products that affect the renin-angiotensin-aldosterone system may cause hyperkalaemia. The risk, that may be fatal, is increased in elderly, in patients with renal insufficiency and in diabetic patients, in patients concomitantly treated with other medicinal products that may increase potassium levels, and/or in patients with intercurrent events. Lithium As with other angiotensin-II receptor antagonists, the combination of lithium and olmesartan medoxomil is not recommended. Primary aldosteronism Patients with primary aldosteronism generally will not respond to antihypertensive drugs acting through inhibition of the renin-angiotensin system. Therefore, the use of olmesartan medoxomil is not recommended in such patients. Pregnancy Angiotensin II antagonists should not be initiated during pregnancy. Unless continued angiotensin II

antagonist's therapy is considered essential, patients planning pregnancy should be changed to alternative anti-hypertensive treatments which have an established safety profile for use in pregnancy. When pregnancy is diagnosed, treatment with angiotensin II antagonists should be stopped immediately and, if appropriate, alternative therapy should be started. Other As with any antihypertensive agent, excessive blood pressure decrease in patients with ischaemic heart disease or ischaemic cerebrovascular disease could result in a myocardial infarction or stroke. This medicinal product contains lactose. Patients with rare hereditary problems of galactose intolerance, the Lapp-lactase deficiency or glucose-galactose malabsorption should not take this medicinal product.

DRUG INTERACTIONS: Interaction studies have only been performed in adults. Effects of other medicinal products on olmesartan medoxomil Other antihypertensive medications: The blood pressure lowering effect of olmesartan medoxomil can be increased by concomitant use of other antihypertensive medications. ACE-inhibitors, angiotensin II receptor blockers or aliskiren Clinical trial data has shown that dual blockade of the renin-angiotensin-aldosterone-system (RAAS) through the combined use of ACE-inhibitors, angiotensin II receptor blockers or aliskiren is associated with a higher frequency of adverse events such as hypotension, hyperkalaemia and decreased renal function (including acute renal failure) compared to the use of a single RAAS-acting agent. Potassium supplements and potassium sparing diuretics: Based on experience with the use of other drugs that affect the renin-angiotensin system, concomitant use of potassium-sparing diuretics, potassium supplements, salt substitutes containing potassium or other drugs that may increase serum potassium levels (e.g. heparin) may lead to increases in serum potassium. Such concomitant use is therefore not recommended. Non-steroidal anti-inflammatory drugs (NSAIDs): NSAIDs (including acetylsalicylic acid at doses> 3 g/day and also COX-2 inhibitors) and angiotensin II receptor antagonists may act synergistically by decreasing glomerular filtration. The risk of the concomitant use of NSAIDs and angiotensin II antagonists is the occurrence of acute renal failure. Monitoring of renal function at the beginning of treatment should be recommended as well as regular hydration of the patient. Additionally, concomitant treatment can reduce the antihypertensive effect of angiotensin II receptor antagonists, leading to their partial loss of efficacy. Bile acid sequestering agent colesevelam Concurrent administration of the bile acid sequestering agent colesevelam hydrochloride reduces the systemic exposure and peak plasma concentration of olmesartan and reduces t1/2. Administration of olmesartan medoxomil at least 4 hours prior to colesevelam hydrochloride decreased the drug interaction effect. Administering olmesartan medoxomil at least 4 hours before the colesevelam hydrochloride dose should be considered.

ADVERSE REACTIONS: Headache, Vertigo, Angina pectoris, Hypotension, Bronchitis, Pharyngitis Cough, Rhinitis, Gastroenteritis, Diarrhoea, Abdominal pain, Nausea, Dyspepsia, Vomiting, Sprue-like enteropathy, Exanthema, Allergic dermatitis, Urticaria, Rash, Pruritus, Angioedema, Arthritis, Back pain, Skeletal pain, Myalgia, Muscle spasm, Haematuria, Urinary tract infection, Acute renal failure, Renal insufficiency, Pain, Chest pain, Peripheral oedema, Influenza-like symptoms, Fatigue, Face oedema, Asthenia, Malaise, Lethargy, Hepatic enzymes increased, Blood urea increased, Blood creatine phosphokinase increased, Blood creatinine increased, Thrombocytopenia, Anaphylactic reaction, Hypertriglyceridaemia, Hyperuricaemia, Hyperkalaemia, Dizziness

MARKETED BY:

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IN/TELSAR CHM 40/12.5/25, 40/12.5/50mg /DEC-21/01/PI

(Additional information is available on request)