OLSAR M

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

Abbreviated Prescribing information for OLSAR M (Olmesartan Medoxomil & Metoprolol Succinate ER tablets**)**

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

WARNING: FETAL TOXICITY

When pregnancy is detected, discontinue the product as soon as possible. Drugs that act directly on the renin-angiotensin system can cause injury and death to the developing fetus.

PHARMACOLOGICAL PROPERTIES:

Mechanism of action: Metoprolol Succinate is a cardio selective beta-adrenergic blocking agent. It has a relatively greater blocking effect on $beta_1$-receptors (i.e. those mediating adrenergic stimulation of heart rate and contractility and release of free fatty acids from fat stores) than on $beta_2$-receptors, which are chiefly involved in bronchi and vasodilation. **Olmesartan Medoxomil** is a potent, orally active, selective angiotensin II receptor (type AT_1) antagonist. It is expected to block all actions of angiotensin II mediated by the AT_1 receptor, regardless of the source or route of synthesis of angiotensin II. The selective antagonism of the angiotensin II (AT_1) receptors results in increases in plasma renin levels and angiotensin I and II concentrations, and some decrease in plasma aldosterone concentrations.

INDICATION: For treatment of essential hypertension.

DOSAGE AND ADMINISTRATION: The recommended starting dose of Olsar M is 10 mg once daily. In patients whose blood pressure is not adequately controlled at this dose, the dose of Olsar M may be increased to 20 mg once daily as the optimal dose. If additional blood pressure reduction is required, Olsar M dose may be increased to a maximum of 40 mg daily or hydrochlorothiazide therapy may be added.

CONTRAINDICATION: Hypersensitivity to the active substance or to any of the excipients Known hypersensitivity to metoprolol, related derivatives, and any other β-blockers or to any of the excipients, Second-or third-degree atrioventricular block, Uncontrolled heart failure, Clinically relevant sinus bradycardia (< 45-50 bpm), Sick sinus syndrome (unless a pacemaker is in situ), Prinzmetal's angina, Myocardial infarction complicated by significant bradycardia, first degree heart block, systolic hypotension (less than 100mmHg) and/or severe heart failure and cardiogenic shock, Severe peripheral arterial disease, Asthma and history of bronchospasm, Untreated phaeochromocytoma, Metabolic acidosis, Concomitant intravenous administration of calcium blockers of the type verapamil or diltiazem or other antiarrhythmics (such as disopyramide) is contraindicated (exception: intensive care unit), Hypotension, Diabetes if associated with frequent episodes of hypoglycaemia, Chronic obstructive pulmonary disease.

WARNINGS & PRECAUTIONS: Metoprolol Succinate: Abrupt cessation of therapy with a beta-blocker should be avoided, metoprolol should be withdrawn gradually over a period of 10 days, Continuation of beta-blockade reduces the risk of arrhythmias during induction and intubation, cardio selective beta blockers may have less effect on lung function than nonselective beta blockers these should be avoided in patients with reversible obstructive airways disease, Metoprolol Tartrate tablets may not be administered to patients with untreated congestive heart failure, When a beta blocker is being taken, a serious, sometimes even life-threatening deterioration in cardiac function can occur, In patients with a phaeochromocytoma, an alpha blocker should be given concomitantly, Beta-blockers mask some of the clinical signs of thyrotoxicosis, Metoprolol may induce or aggravate bradycardia, symptoms of peripheral arterial circulatory disorders and anaphylactic shock, Metoprolol may induce or aggravate bradycardia, symptoms of peripheral arterial circulatory disorders and anaphylactic shock, Beta blockers may unmask myasthenia gravis. **Olmesartan Medoxomil :**Intravascular volume depletion, Other conditions with stimulation of the renin-angiotensin-aldosterone system, Renovascular hypertension , Renal impairment and kidney transplantation, Hepatic impairment, Hyperkalaemia ,

Dual blockade of the renin-angiotensin-aldosterone system (RAAS), Lithium, Primary aldosteronism , Sprue-like enteropathy, Ethnic differences, Pregnancy(Angiotensin II antagonists), antihypertensive agent.

DRUG INTERACTION: Metoprolol Succinate: Anaesthetic drugs **,** hypoglycaemic agent, beta-blockers and calcium channel blockers, NSAIDs, Digitalis Glycosides and/or diuretics, adrenaline or noradrenaline, Class 1 antiarrhythmic drugs, Prostaglandin synthetase inhibiting drugs. **Olmesartan Medoxomil**: Effects of other medicinal products on olmesartan medoxomil antihypertensive medications:ACE-inhibitors, angiotensin II receptor blockers or aliskiren ,Potassium supplements and potassium sparing diuretics, Non-steroidal anti-inflammatory drugs (NSAIDs), Bile acid sequestering agent colesevelam. Effects of olmesartan medoxomil on other medicinal products: Lithium, warfarin, digoxin, an antacid.

ADVERSE REACTIONS: depression, nightmares, nervousness, anxiety, sexual dysfunction or reduced sex drive, inability to think clearly, sleepiness or difficulty in sleeping, tingling or 'pins and needles', difficulty breathing, heart failure, irregular heart rate, palpitation, water retention causing swelling, Raynaud's phenomenon (causing pain, numbness, coldness and blueness of the fingers), diarrhoea or constipation, skin rash, muscle cramps, Lack of energy, impaired kidney function, kidney failure, Some changes in blood test results have also been seen. These include increased potassium levels (hyperkalaemia) and increased levels of compounds related to kidney function, changes in the results of blood tests, effects on blood clotting causing easy or unexplained bruising, changes in personality, confusion, hallucinations, visual disturbances, dry or irritated eyes, ringing in the ears, loss of hearing with high doses, heart conduction problems, chest pain, gangrene in patients with severe poor circulation, runny nose, dry mouth, weight gain sensitivity to light, increased sweating, hair loss, worsening or new psoriasis, joint inflammation (arthritis), disturbances of sexual desire and performance, changes in liver function tests, taste disorders**,** worsening or development of limping, hepatitis (symptoms include fever, sickness and yellowing of the skin or whites of the eyes), Peyronie's syndrome (bending of the penis), symptoms of high levels of the thyroid hormone or low blood sugar may be hidden, increase in blood fats or decrease in cholesterol, retroperitoneal fibrosis (symptoms include lower back pain, high blood pressure), Occurrence of antinuclear antibodies not associated with systemic lupus erythematosus (SLE).

MARKETED BY:

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Torrent Pharmaceuticals Limited.

IN/OLSAR M 20 & 25/50 mg/FEB-26/03/ABPI

(Additional information is available on request)