

OLSAR A

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

Abbreviated Prescribing information for OLSAR A[Amlodipine and Olmesartan Medoxomil tablets I.P]

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

PHARMACOLOGICAL PROPERTIES:

MECHANISM OF ACTION: Alprazolam is a 1,4 benzodiazepine. Alprazolam exerts its effect for the acute treatment of generalized anxiety disorder and panic disorder through binding to the benzodiazepine site of gamma-aminobutyric acid-A (GABAA) receptors in the brain and enhances GABA-mediated synaptic inhibition.

INDICATIONS: For the treatment of mild to moderate hypertension. For the treatment of hypertension alone or with other antihypertensive agents and to use as initial therapy in patients who are likely to need multiple antihypertensive agents to achieve their blood pressure goals.

DOSAGE AND ADMINISTRATION: The recommended dosage of Amlodipine and Olmesartan Medoxomil is 1 tablet per day. Amlodipine and Olmesartan Medoxomil can be taken with or without food. Use of Amlodipine and Olmesartan Medoxomil in patients with severe hepatic impairment is contraindicated.

CONTRAINDICATION: Hypersensitivity to the active substances, to dihydropyridine derivatives or to any of the excipients listed. Second and third trimesters of pregnancy, severe hepatic insufficiency and biliary obstruction. Severe hypotension, shock, obstruction of the outflow tract of the left ventricle, hemodynamically unstable heart failure after acute myocardial infarction.

WARNINGS & PRECAUTIONS: Amlodipine and Olmesartan Medoxomil should be used with caution in patients with conditions such as hypovolaemia, renal impairment, heart failure, and hepatic impairment, and should not be used with dual RAAS blockade, lithium, or in pregnancy. Special caution is also needed in patients with aortic stenosis, primary aldosteronism, and those with severe heart failure, as adverse effects like hypotension, renal dysfunction, hyperkalaemia, and intestinal angioedema may occur.

DRUG INTERACTIONS: Concomitant use of Amlodipine and Olmesartan Medoxomil with other antihypertensives, ACE inhibitors, potassium-altering agents, or lithium requires caution due to increased risks of hypotension, hyperkalaemia, renal dysfunction, and toxicity. Amlodipine interactions with CYP3A4 inhibitors, inducers, and certain drugs like simvastatin, tacrolimus, and cyclosporine may alter drug levels and require monitoring or dose adjustments.

ADVERSE REACTIONS: Leukocytopenia, thrombocytopenia, allergic reaction/ drug hypersensitivity, anaphylactic reaction, hyperglycemia, hyperkalemia, Hypertriglyceridemia, Hyperuricaemia, confusion, depression, insomnia, irritability, libido decreased, mood changes, dizziness, dysgeusia, headache, hypertonia, hypoesthesia, lethargy, paraesthesia, peripheral neuropathy, postural dizziness, sleep disorder, somnolence, syncope, tremor, extrapyramidal disorder, visual disturbance, tinnitus, vertigo, angina pectoris, arrhythmia, myocardial infarction, palpitations, tachycardia, hypotension, orthostatic hypotension, flushing, vasculitis, bronchitis, cough, dyspnoea, pharyngitis, rhinitis, abdominal pain, altered bowel habits, constipation, diarrhea, dry mouth, dyspepsia, gastritis, gastroenteritis, gingival hyperplasia, nausea, pancreatitis, upper abdominal pain, vomiting, sprue like enteropathy, intestinal angioedema, hepatic enzymes increased, hepatitis, jaundice, autoimmune hepatitis, alopecia, angioneurotic oedema, allergic dermatitis, erythema multiforme, exanthema, exfoliative dermatitis, hyperhydrolysis, Photosensitivity, pruritus, purpura, quincke oedema, rash, skin discoloration, steven johnson syndrome, toxic epidermal necrolysis, urticaria, ankle swelling arthralgia, arthritis, back pain, muscle spasm, myalgia, pain in extremity, skeletal pain, acute renal failure, haematuria, increased urinary frequency, micturition disorder, nocturia, pollakiuria, renal insufficiency, urinary tract infection, erectile dysfunction, gynecomastia, asthenia, chest pain, face oedema, fatigue, influenza, malaise, pain, pitting oedema, blood creatinine increased, blood creatinine phosphokinase increased, blood potassium decreased, blood urea increased, blood uric acid increased, gamma glutamyl transferase increased weight decrease, weight increase.

MARKETED BY:



Torrent Pharmaceuticals Limited.

IN/OLSAR A5+20, 5+40/NOV-2025/02/PI.

(Additional information is available on request)