

TOZAM

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

Abbreviated Prescribing information for TOZAM [Losartan potassium 50mg and Amlodipine 5mg Tablets] [Please refer the complete prescribing information available at www.torrentpharma.com]

PHARMACOLOGICAL PROPERTIES: *Losartan:* Losartan Potassium is the first of a new class of antihypertensives. It is an angiotensin II receptor (Type AT1) antagonist. *Amlodipine:* It is a long-acting calcium channel blocker that inhibits the transmembrane influx of calcium ions into vascular smooth muscle and cardiac muscle. **INDICATION:** In the treatment of mild to moderate hypertension in adults.

DOSAGE AND ADMINISTRATION: One tablet of Losartan 50mg and Amlodipine 5mg combination once daily. Tablet may be administered with other antihypertensive agents, and with or without food. Losartan Potassium can be administered once or twice daily with total daily doses ranging from 25 mg to 100 mg. The usual initial antihypertensive oral dose of amlodipine is 5 mg once daily with a maximum dose of 10 mg once daily. **CONTRAINDICATION:** Contraindicated in patients with known hypersensitivity to losartan, amlodipine or any of the excipients. Therapy resistant hypokalaemia or hypercalcaemia. During 2nd and 3rd trimester of pregnancy. Cardiogenic shock, clinically significant aortic stenosis, unstable angina (excluding Prinzmetal's angina). Severe hepatic impairment; cholestasis and biliary obstructive disorders, refractory hyponatraemia, symptomatic hyperuricaemia/gout, severe renal impairment (i.e. creatinine clearance <30 ml/min) and anuria. Do not co-administer aliskiren with losartan in patients with diabetes. **WARNINGS & PRECAUTIONS:** *Losartan:* Fetal Toxicity: It can act on the renin-angiotensin system during the second and third trimesters of pregnancy reduces renal function and increases fetal and neonatal morbidity and death. Caution required for hypotension - volume-depleted patients, hypersensitivity, impaired hepatic function, impaired renal function, electrolyte imbalance and potassium supplements. *Amlodipine:* Hypotension (mainly in patients with aortic stenosis), beta-blocker withdrawal, increased angina or myocardial infarction, impaired hepatic function, Pregnancy and nursing mothers. **DRUG INTERACTIONS:** *Losartan:* Rifampin, an inducer of drug metabolism, decreased the concentrations of losartan and its active metabolite. Fluconazole, an inhibitor of P450 2C9, decreased active metabolite concentration and increased losartan concentration. Potassium-sparing diuretics (e.g., spironolactone, triamterene, amiloride), potassium supplements, or salt substitutes containing potassium may lead to increases in serum potassium. Can interact with Lithium, NSAIDs, including selective COX-2 inhibitors, aliskiren, angiotensin receptor blockers and ACE inhibitors. *Amlodipine:* Grapefruit juice and CYP3A4 inhibitors. **ADVERSE REACTIONS:** *Losartan:* Hepatitis, malaise, thrombocytopenia, angioedema, vasculitis, including Henoch-Schonlein purpura, anaphylactic reactions, hyperkalemia, hyponatremia, rhabdomyolysis, dysgeusia, dry cough, erythroderma, minor increases of blood urea nitrogen (BUN) or serum creatinine, small decreases in hemoglobin and haematocrit, elevations of liver enzymes and/or serum *Amlodipine:* Edema, dizziness, flushing and palpitation, headache, fatigue, nausea, abdominal pain, arrhythmia (including ventricular tachycardia and atrial fibrillation), bradycardia, chest pain, hypotension, peripheral ischemia, syncope, tachycardia, postural dizziness, postural hypotension, vasculitis, hypoesthesia, neuropathy peripheral, paresthesia, tremor, vertigo, anorexia, constipation, dyspepsia, dysphagia, diarrhea, flatulence, pancreatitis, vomiting, gingival hyperplasia, allergic reaction, asthenia, back pain, hot flushes, malaise, pain, rigors, weight gain, weight decrease, arthralgia, arthrosis, muscle cramps, myalgia, sexual dysfunction (male and female), insomnia, nervousness, depression, abnormal dreams, anxiety, depersonalization, dyspnea, epistaxis, angioedema, erythema multiforme, pruritus, rash, rash erythematous, rash maculopapular, abnormal vision, conjunctivitis, diplopia, eye pain, tinnitus, micturition frequency, micturition disorder, nocturia, dry mouth, sweating increased, hyperglycemia, thirst, leukopenia, purpura, thrombocytopenia.

MARKETED BY:



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(Additional information is available on request)