LOSAR BETA

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

Abbreviated Prescribing information for LOSAR BETA [Losartan Potassium & Atenolol Tablets]
[Please refer the complete prescribing information available at www.torrentpharma.com]

PHARMACOLOGICAL PROPERTIES:

MECHANISM OF ACTION: *Losartan Potassium*: Losartan is a synthetic oral angiotensin-II receptor (type AT1) antagonist. Angiotensin II, a potent vasoconstrictor, is the primary active hormone of the renin/angiotensin system and an important determinant of the pathophysiology of hypertension. Angiotensin II binds to the AT1 receptor found in many tissues (e.g. vascular smooth muscle, adrenal gland, kidneys and the heart) and elicits several important biological actions, including vasoconstriction and the release of aldosterone. *Atenolol*: Atenolol is a beta-blocker which is beta1-selective, (i.e. acts preferentially on beta1- adrenergic receptors in the heart).

INDICATIONS: For the treatment of systemic essential hypertension in adults only.

DOSAGE AND ADMINISTRATION: As directed by physician. The dose must always be adjusted to individual requirements of the patients, with the lowest possible starting dosage. For administration by the oral route.

CONTRAINDICATION: Hypersensitivity to the active substance or to any of the excipients. 2nd and 3rd trimester of pregnancy. Severe hepatic impairment. The concomitant use of losartan with aliskiren-containing products is contraindicated in patients with diabetes mellitus or renal impairment (GFR < 60 ml/min/1.73 m^2). Cardiogenic shock. Uncontrolled heart failure. Sick sinus syndrome. Second-or third-degree heart block. Untreated phaeochromocytoma. Metabolic acidosis. Bradycardia (<45 bpm). Hypotension. Severe peripheral arterial circulatory disturbances.

WARNINGS & PRECAUTIONS: *Losartan Potassium*: Patients with a history of angioedema (swelling of the face, lips, throat, and/or tongue) should be closely monitored. Symptomatic hypotension, especially after the first dose and after increasing of the dose, may occur in patients who are volume- and/or sodium-depleted by vigorous diuretic therapy, dietary salt restriction, diarrhoea or vomiting. The concomitant use of potassium-sparing diuretics, potassium supplements and potassium containing salt substitutes with losartan is not recommended. Losartan is not recommended in children with hepatic impairment. As a consequence of inhibiting the renin-angiotensin system, changes in renal function including renal failure have been reported. Concomitant use of losartan and ACE-inhibitors has shown to impair renal function. Therefore, concomitant use is not recommended. In patients with heart failure, with or without renal impairment, there is - as with other medicinal products acting on the renin-angiotensin system - a risk of severe arterial hypotension, and (often acute) renal impairment. As with other vasodilators, special caution is indicated in patients suffering from aortic or mitral stenosis, or obstructive hypertrophic cardiomyopathy. Losartan should not be initiated during pregnancy. *Atenolol*: The dosage should be withdrawn gradually over a period of 7–14 days, to facilitate a reduction in beta-blocker dosage. Although contraindicated in uncontrolled heart failure, may be used in patients whose signs of heart failure have been controlled. Caution must be exercised in patients whose cardiac reserve is poor. Due to its negative effect on conduction time, caution must be exercised if it is given to patients with first-degree heart block. Should be used with caution in the elderly, starting with a lesser dose.

DRUG INTERACTIONS: *Losartan Potassium*: Concomitant use with other substances which may induce hypotension as an adverse reaction (like tricyclic antidepressants, antipsychotics, baclofen and amifostine) may increase the risk of hypotension. . Concomitant use of angiotensin II antagonists or diuretics and NSAIDs may lead to an increased risk of worsening of renal function, including possible acute renal failure, and an increase in serum potassium, especially in patients with poor pre-existing renal function. *Atenolol*: Combined use of beta-blockers and calcium channel blockers with negative inotropic effects, e.g. verapamil and diltiazem, can lead to an exaggeration of these effects particularly in patients with impaired ventricular function and/or sinoatrial or atrioventricular conduction abnormalities. Concomitant use of sympathomimetic agents, e.g. adrenaline (epinephrine), may counteract the effect of beta-blockers. Caution must be exercised when using anaesthetic agents with Atenolol.

ADVERSE REACTIONS: *Losartan Potassium*: anaemia, thrombocytopenia, hypersensitivity reactions, anaphylactic reactions, angioedema, and vasculitis, depression, dizziness, somnolence, headache, sleep disorders, paraesthesia, migraine, dysgeusia, vertigo, tinnitus, palpitations, angina pectoris, syncope, atrial fibrillation,

cerebrovascular accident, hypotension, dyspnoea, cough, abdominal pain, obstipation, diarrhoea, nausea, vomiting, pancreatitis, hepatitis, liver function abnormalities, urticaria, pruritus, rash, photosensitivity, myalgia, arthralgia, rhabdomyolysis, renal impairment, renal failure, erectile dysfunction / impotence, asthenia, fatigue, oedema, malaise, hyperkalaemia, increased alanine aminotransferase, increase in blood urea, serum creatinine, and serum potassium, hyponatraemia, hypoglycaemia. *Atenolol*: Purpura, Sleep disturbances, Mood changes, nightmares, confusion, psychoses and hallucinations, Dry eyes, visual disturbances, Bradycardia, Heart failure deterioration, precipitation of heart block, Cold extremities, Postural hypotension which may be associated with syncope, intermittent claudication may be increased if already present, in susceptible patients Raynaud's phenomenon, Bronchospasm may occur in patients with bronchial asthma or a history of asthmatic complaints, Dry mouth, Hepatic toxicity including intrahepatic cholestasis, Alopecia, psoriasiform skin reactions, exacerbation of psoriasis, skin rashes, Lupus-like syndrome.

MARKETED BY:

TORRENT
PHARMA

Torrent Pharmaceuticals Limited.

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(Additional information is available on request)