

TOLOL AM 50

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

Abbreviated Prescribing information for [Metoprolol Succinate Prolonged release and Amlodipine Tablets I.P.] **TOLOL AM 50**

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

PHARMACOLOGICAL PROPERTIES:

MECHANISM OF ACTION: Metoprolol Succinate is a cardioselective beta-adrenergic blocking agent. It has a relatively greater blocking effect on beta1-receptors (i.e., those mediating adrenergic stimulation of heart rate and contractility and release of free fatty acids from fat stores) than on beta2-receptors, which are chiefly involved in broncho and vasodilation. **Amlodipine Besylate** Amlodipine is a calcium ion influx inhibitor of the dihydropyridine group (slow channel blocker or calcium ion antagonist) and inhibits the transmembrane influx of calcium ions into cardiac and vascular smooth muscle.

INDICATION: TOLOL AM 50 is indicated for the treatment of hypertension.

DOSAGE AND ADMINISTRATION: As directed by the physician. Tablet for oral administration.

CONTRAINDICATION: Metoprolol Succinate Hypersensitivity to dihydropyridine derivatives, amlodipine, metoprolol, related derivatives, any other β -blockers or to any of the excipients. Uncontrolled heart failure. Myocardial infarction complicated by significant bradycardia, first degree heart block, systolic hypotension (less than 100mmHg) and/or severe heart failure and cardiogenic shock. **Amlodipine Besilate** Diabetes if associated with frequent episodes of hypoglycaemia. Asthma and history of bronchospasm.

WARNINGS & PRECAUTIONS: Metoprolol Succinate Abrupt cessation of therapy with a beta-blocker should be avoided especially in patients with ischaemic heart disease. When possible, metoprolol should be withdrawn gradually over a period of 10 days. The safety and efficacy of amlodipine in hypertensive crisis has not been established.

DRUG INTERACTIONS: Metoprolol Succinate Anaesthetic drugs may attenuate reflex tachycardia and increase the risk of hypotension. It may be necessary to adjust the dose of the hypoglycaemic agent in labile or insulin dependent diabetes. **Amlodipine Besylate** Concomitant use of amlodipine with strong or moderate CYP3A4 inhibitors (protease inhibitors, azole antifungals, macrolides like erythromycin or clarithromycin, verapamil or diltiazem) may give rise to significant increase in amlodipine exposure resulting in an increased risk of hypotension.

ADVERSE REACTIONS: Metoprolol Succinate Dizziness, headache, Bradycardia, Orthostatic hypotension (occasionally with syncope), Exertional dyspnea, Nausea and vomiting, abdominal pain, Fatigue, **Amlodipine Besylate** Somnolence, dizziness, headache, Tremor, dysgeusia, syncope, hypoaesthesia, paraesthesia, Visual disturbance, Palpitations, Flushing, Dyspnoea, Abdominal pain, nausea, dyspepsia, altered bowel habits, Ankle swelling, muscle cramps, Fatigue, asthenia.

MARKETED BY:



TORRENT PHARMACEUTICALS LTD.

IN/ TOLOL AM 50 and 5 mg/MAY -20/03/PI

(Additional information is available on request)