

METOCARD AMT 50

For the use of a Registered Medical Practitioner or a Hospital or a Laboratory Only
Abbreviated Prescribing information for METOCARD AMT 50 [Metoprolol (ER), Amlodipine & Telmisartan Tablets (50 mg + 5 mg + 40 mg)]

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

PHARMACOLOGICAL PROPERTIES:

MECHANISM OF ACTION: Metoprolol: Metoprolol is a cardioselective beta-adrenergic blocking agent. It has a relatively greater blocking effect on β_1 -receptors than on β_2 -receptors, which are chiefly involved in broncho and vasodilation. Amlodipine: Amlodipine is a calcium channel blocker that inhibits the transmembrane influx of calcium ions into cardiac and vascular smooth muscle which gives a direct relaxant effect on vascular smooth muscle. Telmisartan: Telmisartan is an orally active and specific angiotensin II receptor (type AT1) antagonist. Telmisartan selectively binds the AT1 receptor. The binding is long-lasting. Telmisartan does not show affinity for other receptors, including AT2 and other less characterised AT receptors. The functional role of these receptors is not known, nor is the effect of their possible overstimulation by angiotensin II, whose levels are increased by telmisartan.

INDICATIONS: For the treatment of uncontrolled essential hypertension with stable coronary artery disease.

DOSAGE AND ADMINISTRATION: Posology: Once daily, with or without food.

Method of administration: Tablet for oral administration.

CONTRAINDICATION: Hypersensitivity to dihydropyridine derivatives, amlodipine, metoprolol, related derivatives, any other β -blockers, to the active substance or to any of the excipients. Metoprolol and Amlodipine Severe hypotension, Shock (including cardiogenic shock), Obstruction of the outflow tract of the left ventricle (e.g., high grade aortic stenosis), Haemodynamically unstable heart failure after acute myocardial infarction, 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, history of bronchospasm, chronic obstructive pulmonary disease, 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), Diabetes if associated with frequent episodes of hypoglycaemia, Telmisartan: Second and third trimesters of pregnancy, Biliary obstructive disorders, Severe hepatic impairment, The concomitant use of Telmisartan with aliskiren-containing products is contraindicated in patients with diabetes mellitus or renal impairment (GFR < 60 ml/min/1.73 m²)

WARNINGS & PRECAUTIONS: Metoprolol Succinate: Abrupt cessation may exacerbate myocardial ischemia, Heart Failure: Worsening cardiac failure may occur. Bronchospastic Disease: Avoid beta-blockers. Concomitant use of glycosides, clonidine, diltiazem and verapamil with beta-blockers can increase the risk of bradycardia. Pheochromocytoma: Initiate therapy with an alpha-blocker. Major Surgery: Avoid initiation of high-dose extended-release metoprolol in patients undergoing noncardiac surgery. Do not routinely withdraw chronic beta-blocker therapy prior to surgery. Hypoglycemia: May increase risk for hypoglycemia and mask early warning signs. Thyrotoxicosis: Abrupt withdrawal in patients with thyrotoxicosis might precipitate a thyroid storm. Peripheral Vascular Disease: Can aggravate symptoms of arterial insufficiency. Patients may be unresponsive to the usual doses of epinephrine used to treat allergic reaction. Telmisartan and Amlodipine: Avoid fetal or neonatal exposure, Hypotension: Correct any volume or salt depletion before initiating therapy. Observe for signs and symptoms of hypotension. Titrate slowly in patients with hepatic or severe renal impairment, Avoid

concomitant use of an ACE inhibitor and angiotensin receptor blocker. Myocardial infarction: Uncommonly, initiating a CCB in patients with severe obstructive coronary artery disease may precipitate myocardial infarction or increased angina.

DRUG INTERACTIONS: Metoprolol: Catecholamine-depleting drugs may have an additive effect when given with beta-blocking agents. CYP2D6 Inhibitors are likely to increase metoprolol concentration. Beta-blockers including metoprolol, may exacerbate the rebound hypertension that can follow the withdrawal of clonidine. Telmisartan and Amlodipine: NSAIDs: Increased risk of renal impairment and loss of antihypertensive effect. If simvastatin is co-administered with amlodipine, do not exceed doses greater than 20 mg daily of simvastatin.

ADVERSE REACTIONS: *Infections and infestations*: Urinary tract infection including cystitis, upper respiratory tract infection including pharyngitis and sinusitis Sepsis including fatal outcome. *Blood and lymphatic system disorders*: Anaemia Eosinophilia ,thrombocytopenia Thrombocytopenia, leukocytopenia, agranulocytosis. *Immune system disorders*: Anaphylactic reaction, hypersensitivity Allergic reactions. *Metabolism and nutrition disorders*: Hyperkalaemia Hypoglycaemia (in diabetic patients). *Psychiatric disorders*: Insomnia, mood changes (including anxiety), depression Nightmares, Nervousness, anxiety, impotence, confusion Hallucinations, personality disorder, Amnesia/ memory impairment. *Nervous system disorders*: Somnolence, dizziness, headache (especially at the beginning of the treatment) Tremor, dysgeusia, syncope, hypoesthesia, paraesthesia Alertness decrease, insomnia paraesthesia. Hypertonia, peripheral neuropathy, Extrapyrarnidal disorder.

MARKETED BY:



TORRENT PHARMACEUTICALS LTD.

IN/METOCARD AMT (50+ 5+40 mg) /JUL 24/01/ABPI

(Additional information is available on request)