METOCARD T

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

Abbreviated Prescribing information for **METOCARD T** [Telmisartan and Metoprolol (ER) Tablets (40 + 25, 40 + 50) mg]

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

WARNING: FETAL TOXICITY

When pregnancy is detected, discontinue the product as soon as possible. Drugs that act directly on the renin-angiotensin system can cause injury and death to the developing fetus.

PHARMACOLOGICAL PROPERTIES:

MECHANISM OF ACTION: Telmisartan is an orally active and specific angiotensin II receptor (type AT1) antagonist. Telmisartan displaces angiotensin II with very high affinity from its binding site at the AT1 receptor subtype, which is responsible for the known actions of angiotensin II. Metoprolol tartrate is a cardioselective beta-adrenergic blocking agent. It has a relatively greater blocking effect on beta1-receptors (ie 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.

INDICATION: METOCARD T is indicated for the treatment of essential hypertension.

DOSAGE AND ADMINISTRATION: Recommended starting dose is 1 tablet of METOCARD T 25 (telmisartan 40mg/metoprolol 25mg) to be administered once daily. Adjust dosage according to blood pressure goals. If blood pressure is not adequately controlled after 2 to 4 weeks of therapy, switch to higher dosage strength i.e., 1 tablet of METOCARD T 50 (telmisartan 40mg/metoprolol 50mg) to be administered once daily. If effect is optimum, continue the same dose. If blood pressure remains uncontrolled, consider a change to more appropriate treatment. It should be preferably administered with or immediately following meals. The tablet should be swallowed whole with water and not to be cut, crushed or chewed or, as prescribed by the physician.

CONTRAINDICATION: Hypersensitivity to telmisartan or metoprolol or related derivatives or any other β-blockers or to any of the excipients, 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)., 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 and history of bronchospasm, 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)., Hypotension, Diabetes if associated with frequent episodes of hypoglycaemia, Chronic obstructive pulmonary disease.

WARNINGS & PRECAUTIONS: ***Telmisartan***: *Pregnancy:* Angiotensin II receptor antagonists should not be initiated during pregnancy. Hepatic impairment these patients can be expected to have reduced hepatic clearance for telmisartan. METOCARD T should be used only with caution in patients with mild to moderate hepatic impairment. Intravascular hypovolaemia Symptomatic hypotension, especially after the first dose of METOCARD T, may occur in patients who are volume and/or sodium depleted by vigorous diuretic therapy, dietary salt restriction, diarrhoea, or vomiting. Such conditions should be corrected before the administration of METOCARD T. the

use of telmisartan is not recommended in primary aldosteronism Patients with primary aldosteronism. This medicinal product contains sorbitol (E420). Patients with rare hereditary problems of fructose intolerance should not take METOCARD T. ***Metoprolol***: Abrupt cessation of therapy with a beta-blocker should be avoided especially in patients with ischaemic heart disease. The patient may be protected against vagal reactions by intravenous administration of atropine. During its withdrawal the patient should be kept under close surveillance. Before a patient undergoes an operation, the anaesthetist must be informed that metoprolol is being taken. Acute initiation of high-dose metoprolol to patients undergoing non-cardiac surgery should be avoided, since it has been associated with bradycardia, hypotension and stroke including fatal outcome in patients with cardiovascular risk factors.

DRUG INTERACTIONS: ***Telmisartan:*** *digoxin****:*** Co-administered with digoxin, median increases in digoxin peak plasma concentration. *Lithium****:*** Reversible increases in serum lithium concentrations and toxicity, NSAIDs, Diuretics, and Corticosteroids. ***Metoprolol:*** Anaesthetic drugs may attenuate reflex tachycardia and increase the risk of hypotension, Hypoglycaemic agents, CCBs, MAO inhibitors, Adrenaline and Noradrenaline, Enzyme inducing agents etc.

ADVERSE REACTIONS: ***Telmisartan***: Urinary tract infection including cystitis, upper respiratory tract infection including pharyngitis and sinusitis, Sepsis including fatal outcome, Anaemia, Eosinophilia, thrombocytopenia, , Anaphylactic reaction, hypersensitivity, Hyperkalaemia, Hypoglycaemia (in diabetic patients), , Insomnia, depression, Anxiety, , Syncope, Somnolence, , Visual disturbance, , Vertigo, Bradycardia, Tachycardia, , Hypotension, orthostatic hypotension, Dyspnoea, cough, Interstitial lung disease4, Abdominal pain, diarrhoea, dyspepsia, flatulence, vomiting, Dry mouth, stomach discomfort, dysgeusia, Hepatic function abnormal/liver disorder, Pruritus, hyperhidrosis, rash, Angioedema (also with fatal outcome), eczema, erythema, urticaria, drug eruption, toxic skin eruption, Back pain (e.g. sciatica), muscle spasms, myalgia, Arthralgia, pain in extremity, tendon pain (tendinitis like symptoms), , Renal impairment including acute renal failure, , Chest pain, asthenia (weakness), Influenza-like illness, Blood creatinine increased, Haemoglobin decreased, blood uric acid increased, hepatic enzyme increased, blood creatine phosphokinase increased. ***Metoprolol:*** Thrombocytopenia, agranulocytosis, Depression, nightmares, Nervousness, anxiety, impotence, Hallucinations, personality disorder, Amnesia / memory impairment, , Dizziness, headache, Alertness decreased, somnolence or insomnia, paraesthesia, Visual disturbance (e.g. blurred vision, dry eyes and/or eye irritation, Tinnitus, and, in doses exceeding those recommended, "hearing disorders (eg. hypoacusis or deafness), Bradycardia, Heart failure, cardiac arrhythmias, palpitation, Cardiac conduction disorders, precordial pain, Increase in existing intermittent claudication, , Orthostatic hypotension (occasionally with syncope), Oedema, Raynaud's phenomenon, Gangrene in patients with preexisting severe peripheral circulatory disorders, , Exertional dyspnea, Bronchospasm(which may occur in patients without a history of obstructive lung disease), Rhinitis, , Nausea and vomiting, abdominal pain, Diarrhoea or constipation, Dry mouth, Retroperitoneal fibrosis, Hepatitis, Skin rash (in the form of urticaria, psoriasiform and dystrophic skin lesions), Photosensitivity, hyperhidrosis, alopecia, worsening of psoriasis, Occurrence of antinuclear antibodies (not associated with SLE), Muscle cramps, Arthritis, Disturbances of Libido and potency, Peyronie's disease, Fatigue, Dysgeusia (Taste disturbances), Weight increase, liver function test abnormal

MARKETED BY:

TORRENT PHARMACEUTICALS LTD.

IN/METOCARD T (40+25, 40+50) mg /May-2024/01/ABPI

(Additional information is available on request)