TELSAR BETA

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

Abbreviated Prescribing information for TELSAR BETA

(Telmisartan and Metoprolol ER Tablets) [Please refer the complete prescribing information for details].

PHARMACOLOGICAL PROPERTIES:

Mechanism of Action: ***Telmisartan*****:** Telmisartan blocks the vasoconstrictor and aldosterone-secreting effects of angiotensin II by selectively blocking the binding of angiotensin II to the AT1 receptor in many tissues, such as vascular smooth muscle and the adrenal gland. Its action is, therefore, independent of the pathways for angiotensin II synthesis. Telmisartan has much greater affinity (more than 3000-fold) for the AT1 receptor than for the AT2 receptor. Telmisartan does not inhibit the angiotensin converting enzyme [ACE (kininase II)]; hence, it does not affect the response to bradykinin. ***Metoprolol*****:** Metoprolol is a beta-1 selective beta blocker. It has a relatively greater blocking effect on beta receptors (i.e. those mediating adrenergic stimulation of heart rate and contractility and release of the fatty acids from fat stores) than on beta receptors which are chiefly involved in broncho and vasodilation. Metoprolol only exhibits insignificant membrane stabilising effect and has no agonist effect. Metoprolol reduces or blocks the stimulating effect of catecholamines (particularly released in case of physical or mental stress) on the heart. Metoprolol reduces tachycardia, decreases the cardiac output and the contractility, and lowers the blood pressure.

INDICATIONS: TELSAR BETA is indicated for the treatment of essential hypertension.

DOSAGE AND ADMINISTRATION: As directed by the Physician. Tablets should be taken orally.

CONTRAINDICATION: TELSAR BETA is contraindicated in patients with known hypersensitivity to telmisartan or metoprolol or related derivatives or any other β-blockers or to any of the excipients, in 2^{nd} and 3^{rd} trimester of pregnancy, patient with biliary obstructive disorders. 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: ***Telmisartan*****:** *Pregnancy* Angiotensin II receptor antagonists should not be initiated during pregnancy. When pregnancy is diagnosed, treatment with angiotensin II receptor antagonists should be stopped immediately, and, if appropriate, alternative therapy should be started. *Hepatic impairment* these patients can be expected to have reduced hepatic clearance for telmisartan. TELSAR BETA should be used only with caution in patients with mild to moderate hepatic impairment. *Intravascular hypovolaemia* Symptomatic hypotension, especially after the first dose of TELSAR BETA, 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 TELSAR BETA. *Primary aldosteronism* Patients with primary aldosteronism generally will not respond to antihypertensive medicinal products acting through inhibition of the renin-angiotensin system. Therefore, the use of telmisartan is not recommended. *Sorbitol* This medicinal product contains sorbitol (E420). Patients with rare hereditary problems of fructose intolerance should not take TELSAR BETA. ***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. In case of unstable or insulin dependent diabetes mellitus, it may be necessary to adjust the hypoglycaemic treatment (because of the likelihood of severe hypoglycaemic conditions).

DRUG INTERACTIONS: ***Telmisartan*****:** *Digoxin* When initiating, adjusting, and discontinuing telmisartan, monitor digoxin levels in order to maintain levels within the therapeutic range. Potassium sparing diuretics e.g. spirinolactone, eplerenone, triamterene, or amiloride, potassium supplements, or potassium-containing salt substitutes may lead to a significant increase in serum potassium. If concomitant use is indicated because of documented hypokalaemia, they should be used with caution and with frequent monitoring of serum potassium. *Lithium* Reversible increases in serum lithium concentrations and toxicity have been reported during concomitant administration of lithium with angiotensin converting enzyme inhibitors, and with angiotensin II receptor antagonists, including telmisartan.. NSAIDs may reduce the antihypertensive effect of angiotensin II receptor antagonists. ***Metoprolol*****:** Anaesthetic drugs may attenuate reflex tachycardia and increase the risk of hypotension. Metoprolol therapy should be reported to the anaesthetist before the administration of a general anaesthetic. Like all beta-blockers, metoprolol should not be given in combination with calcium channel blockers. NSAIDs (especially indometacin) may reduce the antihypertensive effects of beta-blockers possibly by inhibiting renal prostaglandin synthesis and/or causing sodium and fluid retention.

ADVERSE REACTIONS: ***Telmisartan*****:** Urinary tract infection including cystitis, upper respiratory tract infection including pharyngitis and sinusitis, Sepsis including fatal outcome1, Anaemia, Eosinophilia, thrombocytopenia, , Anaphylactic reaction, hypersensitivity, Hyperkalaemia, Hypoglycaemia (in diabetic patients), , Insomnia, depression, Anxiety, , Syncope, Somnolence, , Visual disturbance, , Vertigo, Bradycardia, Tachycardia, , Hypotension2, 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:

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IN/TELSAR BETA 40, 25/50 mg/MAY-20/01/ABPI

(Additional information is available on request)