CORBIS T/TELSAR BISO

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

Abbreviated Prescribing information for Corbis T/Telsar Biso

(Bisoprolol Fumarate & Telmisartan Tablets (2.5+40mg, 5+40mg) [Please refer the complete prescribing information for details].

PHARMACOLOGICAL PROPERTIES:

Mechanism of Action:

Telmisartan: 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. Telmisartan does not exhibit any partial agonist activity at the AT1 receptor. 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. In human, an 80 mg dose of telmisartan almost completely inhibits the angiotensin II evoked blood pressure increase. The inhibitory effect is maintained over 24 hours and still measurable up to 48 hours. **Bisoprolol:** Bisoprolol is a highly beta1-selective-adrenoceptor blocking agent, lacking intrinsic stimulating and relevant membrane stabilising activity.

INDICATIONS: It is indicated for the treatment of mild to moderate hypertension

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

CONTRAINDICATION: Hypersensitivity to the active substance 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). Acute heart failure or during episodes of heart failure decompensation requiring i.v. Inotropic therapy, Cardiogenic shock, Second or third degree AV block, Sick sinus syndrome, Sinoatrial block, Symptomatic bradycardia, Symptomatic hypotension, Severe bronchial asthma, Severe forms of peripheral arterial occlusive disease or severe forms of raynaud's syndrome, Untreated phaeochromocytoma and Metabolic acidosis,

WARNINGS & PRECAUTIONS: Telmisartan: *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. *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.) **Bisoprolol:** There is no therapeutic experience of bisoprolol treatment of heart failure in patients with the following diseases and conditions: Insulin dependent diabetes mellitus (type I), Severely impaired renal function, Severely impaired hepatic function, Restrictive cardiomyopathy, Congenital heart disease, Haemodynamically significant organic valvular disease, Myocardial infarction within 3 months, Bisoprolol must be used with caution in: Bronchospasm (bronchial asthma, obstructive airways diseases), Diabetes mellitus with large fluctuations in blood glucose values; Symptoms of hypoglycaemia can be masked, Strict fasting, Ongoing desensitisation therapy. As with other beta-blockers, bisoprolol may increase both the sensitivity towards allergens and the severity of anaphylactic reactions. Epinephrine treatment does not always yield the expected therapeutic effect, First degree AV block, Prinzmetal's angina: Cases of coronary vasospasm have been

observed. Despite its high beta1-selectivity, angina attacks cannot be completely excluded when bisoprolol is administered to patients with Prinzmetal's angina, Peripheral arterial occlusive disease. Aggravation of symptoms may occur especially when starting therapy, General anaesthesia

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. **Bisoprolol:** *Combinations not recommended*: Calcium antagonists of the verapamil type and to a lesser extent of the diltiazem type, Class I antiarrhythmic drugs (e.g. quinidine, disopyramide; lidocaine, phenytoin; flecainide, propafenone), Centrally acting antihypertensive drugs such as clonidine and others (e.g. methyldopa, moxonodine, rilmenidine).*Combinations to be used with caution*: Calcium antagonists of the dihydropyridine type such as felodipine and amlodipine, Class-III antiarrhythmic drugs (e.g. amiodarone), Topical beta-blockers, Parasympathomimetic drugs, Insulin and oral antidiabetic drugs, Anaesthetic agents, Digitalis glycosides, Non-steroidal anti-inflammatory drugs (NSAIDs), β-Sympathomimetic agents (e.g. isoprenaline, dobutamine), antihypertensive agents as well as with other drugs with blood pressure lowering potential (e.g. tricyclic antidepressants, barbiturates, phenothiazines) may increase the risk of hypotension. *Combinations to be considered:* Mefloquine, monoamine oxidase inhibitors (except MAO-B inhibitors).

ADVERSE REACTIONS: Telmisartam: 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. **Bisoprolol:** Bradycardia, worsening of pre-existing heart failure, AV-conduction disturbances, sleep disorders, depression, nightmares, hallucinations, dizziness, headache, syncope, dry eyes, impaired vision, conjunctivitis, hearing disorders, feeling of coldness or numbness in the extremities, hypotension, orthostatic hypotension, Cyanosis of extremities, paraesthesia bronchospasm in patients with bronchial asthma or a history of obstructive airways disease, allergic rhinitis, as nausea, vomiting, diarrhoea, constipation, hepatitis, erectile dysfunction, hypersensitivity reactions (itching, rash), alopecia, muscular weakness and cramps, asthenia, increased liver enzymes, Perspiration, Oedema, lassitude fatigue, Increased triglycerides, angioedema.

MARKETED BY:

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IN/ CORBIS T/TELSAR BISO 2.5+40mg, 5+40mg/Dec-22/01/ABPI

(Additional information is available on request)