TELSAR AMH

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

Abbreviated Prescribing information for TELSAR AMH (Telmisartan, Amlodipine & Hydrochlorothiazide Tablets 40/5/12.5 & 80/5/12.5)

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

PHARMACOLOGICAL PROPERTIES:

MECHANISM OF ACTION: ***Telmisartan:*** Telmisartan is an orally effective and specific angiotensin II receptor subtype 1 (AT_1) antagonist. ***Amlodipine:*** The mechanism of the antihypertensive action of amlodipine is due to a direct relaxant effect on vascular smooth muscle. The precise mechanism by which amlodipine relieves angina has not been fully determined but amlodipine reduces total ischaemic burden. The mechanism of action of amlodipine also probably involves dilatation of the main coronary arteries and coronary arterioles, both in normal and ischaemic regions. This dilatation increases myocardial oxygen delivery in patients with coronary artery spasm (Prinzmetal's or variant angina). ***Hydrochlorothiazide:*** The mechanism of the antihypertensive effect of thiazide diuretics is not fully known. Thiazides have an effect on the renal tubular mechanisms of electrolyte reabsorption, directly increasing excretion of sodium and chloride in approximately equivalent amounts.

INDICATIONS: It is indicated for the treatment of patients with Hypertension.

DOSAGE AND ADMINISTRATION: Dose: As directed by the Physician. Usual Dose: 1 tablet of TELSAR AMH to be administered once daily. Adjust dosage according to blood pressure goals. If adequate response is not achieved after 2 to 4 weeks of therapy, dose may be increased. The dosage, however, should be individualized. TELSAR AMH Tablets may be administered with or without food. The tablet should be swallowed whole with water and not to be cut, crushed or chewed. Method of administration: Tablet for oral administration.

CONTRAINDICATION: Hypersensitivity to the active substance, dihydropyridine derivatives, amlodipine or to any of the excipients; Second and third trimesters of pregnancy; Biliary obstructive disorders; Severe hepatic impairment; 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.; 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*: Fetal Toxicity: When pregnancy is detected, Telmisartan should be discontinued as soon as possible, it can cause injury and even death to the developing fetus, when used during second and third trimesters of pregnancy. Pregnancy: It should not be initiated during pregnancy. Hepatic impairment: It should not be given to patients with cholestasis, biliary obstructive disorders or severe hepatic impairment since telmisartan is mostly eliminated with the bile. Renovascular hypertension: There is an increased risk of severe hypotension and renal insufficiency. Renal impairment and kidney transplantation: It must not be used in patients with severe renal impairment. Intravascular hypovolaemia: Symptomatic hypotension, especially after the first dose of Telmisartan, may occur in patients who are volume and/or sodium depleted by vigorous diuretic therapy, dietary salt restriction, diarrhoea, or vomiting. Dual blockade of the renin-angiotensin-aldosterone system (RAAS): There is evidence that the concomitant use of ACE-inhibitors, angiotensin II receptor blockers or aliskiren increases the risk of hypotension, hyperkalaemia and decreased renal function. Primary aldosteronism: Patients with primary aldosteronism generally will not respond to antihypertensive medicinal products acting through inhibition of the renin-angiotensin system. Aortic and mitral valve stenosis, obstructive hypertrophic cardiomyopathy: As with other vasodilators, special caution is indicated in patients suffering from aortic or mitral stenosis, or obstructive hypertrophic cardiomyopathy. Patients with heart failure: They should be treated with caution. Metabolic and endocrine effects: Thiazide therapy may impair glucose tolerance, whereas hypoglycaemia may occur in diabetic patients under insulin or antidiabetic therapy and telmisartan treatment. Electrolyte imbalance: As for any patient receiving diuretic therapy, periodic determination of serum electrolytes should be performed at appropriate intervals. Non-melanoma skin cancer: An increased risk of non-melanoma skin cancer with increasing cumulative dose of hydrochlorothiazide (HCTZ). Elderly patients: In the elderly increase of the dosage should take place with care.

DRUG INTERACTIONS: TELSAR AMH shows drug interaction with Digoxin, Potassium sparing diuretics or potassium supplements, Lithium, Non-steroidal anti-inflammatory medicinal products, Diuretics (thiazide or loop diuretics), Other antihypertensive agents: Baclofen, amifostine. Furthermore, orthostatic hypotension may be

aggravated by alcohol, barbiturates, narcotics, or antidepressants. Corticosteroids (systemic route) Reduction of the antihypertensive effect. *Effects of other medicinal products on amlodipine:* CYP3A4 inhibitors, CYP3A4 inducers, Dantrolene (infusion), *Effects of amlodipine on other medicinal products:* Tacrolimus, Mechanistic Target of Rapamycin (mTOR) Inhibitors, Cyclosporine, Simvastatin.

ADVERSE REACTIONS: ***Very Common***: Oedema. ***Common***: Somnolence, Dizziness, Visual Disturbance, Palpitations, Flushing, Dyspnoea, Abdominal Pain, Nausea, Ankle Swelling, Muscle Cramps, Fatigue, Asthenia. ***Uncommon***: Anaemia, Hyperkalaemia, Depression, Mood Changes, Tremor, Dysgeusia, Tinnitus, Vertigo, Arrhythmia, Hypotension, Cough, Rhinitis, Vomiting, Dry Mouth, Alopecia, Purpura, Arthralgia, Myalgia, Micturition Disorder, Nocturia, Impotence, Gynaecomastia, Chest Pain, Pain, Weight Increased, Weight Decreased. ***Rare:*** Eosinophilia, Thrombocytopenia, Anaphylactic Reaction, Hypersensitivity, Hyperglycaemia, Confusion, Stomach Discomfort, Dysgeusia, Hepatic Function Abnormal/Liver Disorder, Angioedema, Eczema, Influenza-Like Illness, Haemoglobin Decreased, Blood Uric Acid Increased. ***Very Rare:*** Leukocytopenia, Allergic Reactions, Hypertonia, Peripheral Neuropathy, Myocardial Infarction, Vasculitis, Interstitial Lung Disease, Pancreatitis, Gastritis, Hepatitis, Jaundice, Erythema Multiforme, Stevens-Johnson Syndrome. ***Not Known:*** Toxic Epidermal Necrolysis.

MARKETED BY:

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IN/TELSAR AMH 40 mg+5 mg+12.5 mg &80 mg +5 mg+12.5 mg/Apr-2024/01/ABPI

(Additional information is available on request)