TELSAR A

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

Abbreviated Prescribing information for TELSAR A (Telmisartan Amlodipine Tablets I.P.) [Please refer the complete prescribing information for details].

PHARMACOLOGICAL PROPERTIES:

Mechanism of Action: ***Telmisartan*****:** Telmisartan is a nonpeptide angiotensin II receptor antagonist which selectively and insurmountably inhibits angiotensin II AT1 receptor subtype without affecting other systems involved in cardiovascular regulation. Telmisartan blocks the vasoconstrictor and aldosterone secretion effect of angiotensin II by selectively blocking the binding of angiotensin II to the AT1 receptor in many tissues. Its action is therefore independent of the pathways for angiotensin II synthesis. ***Amlodipine:*** Amlodipine is a dihydropyridine calcium channel-blocking agent structurally related to nifedipine. The mechanism of action of amlodipine is similar to that of other calcium channelblocking agents. Amlodipine inhibits the transmembrane influx of calcium ions into vascular smooth muscle and cardiac muscle. Amlodipine binds to both dihydropyridine and non dihydropyridine binding sites. The contractile processes of cardiac muscle and vascular smooth muscle are dependent upon the movement of extracellular calcium ions into these cells through specific ion channels. Amlodipine inhibits calcium ion influx across cell membranes selectively, with a greater effect on vascular smooth muscle cells than on cardiac muscle cells

INDICATIONS Combination of Telmisartan and Amlodipine is indicated for the treatment of essential hypertension.

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

CONTRAINDICATION: TELSAR A is contraindicated in patients with known hypersensitivity to the active substance, Patients with anuria, Pregnant and lactating females, Hereditary or idiopathic angioedema

WARNINGS & PRECAUTIONS: ***Telmisartan*****:** Hypotension in volume and salt depleted Patients, Hyperkalemia, Increased Angina and/or Myocardial Infarction, CHF, Hepatic Failure, Renal Function Impairment, Dual Blockade of the Renin-Angiotensin-Aldosterone System, Heart Failure,

DRUG INTERACTIONS***: Telmisartan:*** Telmisartan is not metabolized by any cytochrome P450 (CYP) isoenzymes hence has low potential to interfere with metabolism of drugs, metabolized through this system, except for possible inhibitor of the metabolism of drug metabolized by CYP2C19. Digoxin, Warfarin, Lithium, Ramipril and Ramiprilat, Co-administration of telmisartan had no effect on steady state pharmacokinetics of amlodipine, glibenclamide, ibuprofen, paracetamol, hydrochlorothiazide, simvastatin and glyburide. ***Amlodipine:*** Amlodipine had no effect on the protein binding of drugs tested (digoxin, phenytoin, warfarin, and indomethacin). Amlodipine had no clinically significant pharmacokinetic interaction with cimetidine, antacid, sildenafil, digoxin, warfarin or ethanol. In clinical trials, amlodipine has been safely administered with thiazide diuretics, beta-blockers, angiotensin-converting enzyme inhibitors, long-acting nitrates, sublingual nitroglycerin, digoxin, warfarin, non-steroidal anti-inflammatory drugs, antibiotics, and oral hypoglycemic drugs.

ADVERSE REACTIONS: ***Telmisartan*****:** Anaemia, Eosinophilia, thrombocytopenia, Leukocytopenia, Anaphylactic reaction, hypersensitivity, Allergic reactions, Hyperkalaemia , Hyperglycaemia (in diabetic patients), Depression, mood changes (including anxiety), insomnia, Confusion, Somnolence, dizziness, headache (especially at the beginning of the treatment), Tremor, dysgeusia, syncope, hypoaesthesia, paraesthesia, Hypertonia, peripheral neuropathy, Visual disturbance (including diplopia), Tinnitus, Vertigo, Palpitations, Arrhythmia (including bradycardia, ventricular tachycardia and atrial fibrillation), Myocardial infarction, Flushing, Hypotension, orthostatic hypotension, Vasculitis, Dyspnoea, Cough, rhinitis, Interstitial lung disease, Abdominal pain, nausea, dyspepsia, flatulence, altered bowel habits (including diarrhoea and constipation), Vomiting, dry mouth, Stomach discomfort, dysgeusia, Pancreatitis, gastritis, gingival hyperplasia, Hepatic function abnormal/liver disorder, Hepatitis, jaundice, hepatic enzyme increased, Alopecia, purpura, skin discolouration, hyperhidrosis, pruritus, rash, exanthema, urticarial, Angioedema (also with fatal outcome), eczema, erythema, urticaria, drug eruption, toxic skin eruption, Erythema multiforme, exfoliative dermatitis, Stevens-Johnson syndrome, Quincke oedema, photosensitivity, Toxic epidermal necrolysis, Ankle swelling, muscle cramps, Arthralgia, myalgia, back pain (e.g. sciatica), pain in extremity, tendon pain (tendinitis like symptoms), Micturition disorder, nocturia, increased urinary frequency, renal impairment including acute renal

failure, Impotence, gynaecomastia, Oedema, Fatigue, asthenia, Chest pain, pain, malaise, Influenza-like illness, Weight increased, weight decreased, blood creatinine increased, Haemoglobin decreased, blood uric acid increased, hepatic enzyme increased, phosphokinase increased. ***Amlodipine:*** Leukocytopenia, thrombocytopenia, Allergic reactions, Hyperglycaemia, Depression, mood changes (including anxiety), insomnia, Confusion, Somnolence, dizziness, headache (especially at the beginning of the treatment), Tremor, dysgeusia, syncope, hypoaesthesia, paraesthesia, Hypertonia, peripheral neuropathy, Visual disturbance (including diplopia), Tinnitus, Palpitations, Arrhythmia (including bradycardia, ventricular tachycardia and atrial fibrillation), Myocardial infarction, Flushing, Hypotension, Vasculitis, Dyspnoea, Cough, rhinitis, Abdominal pain, nausea, dyspepsia, altered bowel habits (including diarrhoea and constipation), Vomiting, dry mouth, Pancreatitis, gastritis, gingival hyperplasia, Hepatitis, jaundice, hepatic enzyme increased*, Alopecia, purpura, skin discolouration, hyperhidrosis,, pruritus, rash, exanthema, urticarial, Angioedema, erythema multiforme, exfoliative dermatitis, Stevens-Johnson syndrome, Quincke oedema, photosensitivity, Toxic epidermal necrolysis. Ankle swelling, muscle cramps, Arthralgia, myalgia, back pain, Micturition disorder, nocturia, increased urinary frequency, Impotence, gynaecomastia, Oedema, Fatigue, asthenia, Chest pain, pain, malaise, Weight increased, weight decreased

MARKETED BY:

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IN/ TELSAR A 40, 80 and 5mg/APR-19/01/ABPI

(Additional information is available on request)