TELSAR LN

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

Abbreviated Prescribing information for TELSAR LN
(Telmisartan and Cilnidipine Tablets) [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 AT) antagonist. Telmisartan displaces angiotensin II with very high affinity from its binding site at the AT receptor subtype, which is responsible for the known actions of angiotensin II. Telmisartan does not exhibit any partial agonist activity at the AT receptor. Telmisartan selectively binds the AT receptor. The binding is long-lasting. Telmisartan does not show affinity for other receptors, including AT and other less characterised AT receptors. The functional role of these receptors is not known, nor is the effect of their possible overstimulation by angiotensin II, whose levels are increased by telmisartan. Plasma aldosterone levels are decreased by telmisartan. Telmisartan does not inhibit human plasma renin or block ion channels. Telmisartan does not inhibit angiotensin converting enzyme (kininase II), the enzyme which also degrades bradykinin. Therefore it is not expected to potentiate bradykinin-mediated adverse effects. 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**.** ***Cilnidipine***: is a novel dihydropyridine calcium antagonist and its calcium antagonistic activity is lasting longer than those of Nifedipine and Nicardipine. Cilnidipine has been used for the treatment of hypertension and hypertensive-associated vascular disorders. Its adult dose is about 40 to 80 mg once daily. Cilnidipine has a very low solubility (BCS Class-II drug Low solubility high permeability) and compliance to the medication is always very poor.

INDICATIONS: In mild to moderate hypertension.

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

CONTRAINDICATION: Hypersensitivity to the active substance, dihydropyridine derivatives, Cilnidipine or to any of the excipients • Second and third trimesters of pregnancy • Biliary obstructive disorders • Severe hepatic impairment • Severe hypotension. The concomitant use of TELSAR LN with aliskiren-containing products is contraindicated in patients with diabetes mellitus or renal impairment (GFR < 60 ml/min/1.73 m)

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 LN 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 LN, 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 LN. *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 LN. *Ethnic differences* as observed for angiotensin converting enzyme inhibitors, telmisartan and the other angiotensin II receptor antagonists are apparently less effective in lowering blood pressure in black people than in non-blacks, possibly because of higher prevalence of low-renin states in the black hypertensive population. *Other* As with any antihypertensive agent, excessive reduction of blood pressure in patients with ischaemic cardiopathy or ischaemic cardiovascular disease could result in a myocardial infarction or stroke. ***Cilnidipine:*** Hypotension, poor cardiac reserve and

heart failure. Sudden withdrawal may exacerbate angina. Discontinue in patients who experience ischemic pain following administration. Pregnancy and lactation.

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. ***Cilnidipine***: can interact with aldesleukin, quinidine, phenytoin, rifampicin, erythromycin, other anti-hypertensive drugs and anti-psychotic drugs.

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 disease, 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. ***Cilnidipine:*** Dizziness, Flushing, Headache, Hypotension, Peripheral oedema, Tachycardia, Palpitations, GI disturbances, Increased micturition frequency, Lethargy.

MARKETED BY:

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(Additional information is available on request)