TELSAR

For the use of a Registered Medical Practitioner or a Hospital or a Laboratory only
Abbreviated Prescribing information for **TELSAR (**Telmisartan Tablets I.P.) [Please refer the complete prescribing information for details]

PHARMACOLOGICAL PROPERTIES:
Mechanism of Action: ***Telmisartan:*** is an orally active and specific angiotensin II receptor (type AT_1) antagonist. Telmisartan displaces angiotensin II with very high affinity from its binding site at the AT_1 receptor subtype, which is responsible for the known actions of angiotensin II. Telmisartan does not exhibit any partial agonist activity at the AT_1 receptor. Telmisartan selectively binds the AT_1 receptor. The binding is long-lasting. Telmisartan does not show affinity for other receptors, including AT_2 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 measurableup to 48 hours.
INDICATIONS: - For the treatment of hypertension. - For the prevention of cardiovascular morbidity and mortality in patient 55 years older at high risk of cardiovascular disease
Dosage and Administration: Dosage: As directed by the Physician.
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 m^2).
WARNINGS & PRECAUTION: When pregnancy is detected, discontinue the product as soon as possible. Drugs that act directly on the renin-angiotensin system can cause injury and death to the developing fetus. *Pregnancy:* Angiotensin II receptor antagonists should not be initiated during pregnancy. Unless continued angiotensin II receptor antagonist therapy is considered essential, *hepatic impairment:* Telsar is not to 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 when patients with bilateral renal artery stenosis or stenosis. *Renal impairment and kidney transplantation:* When Telsar is used in patients with impaired renal function, periodic monitoring of potassium and creatinine serum levels is recommended. *Intravascular hypovolaemia:* Symptomatic hypotension, especially after the first dose of Telsar, may occur in patients who are volume and/or sodium depleted by vigorous diuretic therapy, dietary salt restriction, diarrhoea, or vomiting.
DRUG INTERACTIONS: *Digoxin:* When telmisartan was co-administered with digoxin, median increases in digoxin peak plasma concentration (49%) and in trough concentration (20%) were observed. Angiotensin II receptor antagonists such as telmisartan, attenuate diuretic induced potassium loss. Potassium sparing diuretics e.g. spironolactone, eplerenone, triamterene, or amiloride, potassium supplements, or potassium-containing salt substitutes may lead to a significant increase in 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. *Non-steroidal anti-inflammatory medicinal products:*

NSAIDs (i.e. acetylsalicylic acid at anti-inflammatory dosage regimens, COX-2 inhibitors and non-selective NSAIDs) may reduce the antihypertensive effect of angiotensin II receptor antagonists. *Diuretics (thiazide or loop diuretics)* Prior treatment with high dose diuretics such as furosemide (loop diuretic) and hydrochlorothiazide (thiazide diuretic) may result in volume depletion, and in a risk of hypotension when initiating therapy with telmisartan.

ADVERSE REACTIONS: Urinary tract infection including cystitis, upper respiratory tract infection including pharyngitis and sinusitis. Sepsis including fatal outcome, Anaemia, Eosinophilia, thrombocytopenia, Anaphylactic reaction, hypersensitivity, Hyperkalaemia, 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

MARKETED BY:

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IN/ TELSAR 20, 40, and 80 mg /Dec-19/01/ AbPI

(Additional information is available on request)