

TELSAR AM 80 / TELDAY 80 AM

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

Abbreviated Prescribing information for TELSAR AM 80 / TELDAY 80 AM [Telmisartan 80 mg and Amlodipine 5 mg Tablets I.P]

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

PHARMACOLOGICAL PROPERTIES:

MECHANISM OF ACTION: *Telmisartan* Angiotensin II is formed from angiotensin I in a reaction catalyzed by angiotensin converting enzyme (ACE, kininase II). Angiotensin II is the principal pressor agent of the renin-angiotensin system, with effects that include vasoconstriction, stimulation of synthesis and release of aldosterone, cardiac stimulation, and renal reabsorption of sodium. Telmisartan blocks the vasoconstrictor and aldosterone-secreting effects of angiotensin II by selectively blocking the binding of angiotensin II to the AT₁ receptor in many tissues, such as vascular smooth muscle and the adrenal gland. Its action is therefore independent of the pathways for angiotensin II synthesis. There is also an AT₂ receptor found in many tissues, but AT₂ is not known to be associated with cardiovascular homeostasis. Telmisartan has much greater affinity (>3,000 fold) for the AT₁ receptor than for the AT₂ receptor. Blockade of the renin-angiotensin system with ACE inhibitors, which inhibit the biosynthesis of angiotensin II from angiotensin I, is widely used in the treatment of hypertension. ACE inhibitors also inhibit the degradation of bradykinin, a reaction also catalyzed by ACE. Because telmisartan does not inhibit ACE (kininase II), it does not affect the response to bradykinin. Whether this difference has clinical relevance is not yet known. Telmisartan does not bind to or block other hormone receptors or ion channels known to be important in cardiovascular regulation. Blockade of the angiotensin II receptor inhibits the negative regulatory feedback of angiotensin II on renin secretion, but the resulting increased plasma renin activity and angiotensin II circulating levels do not overcome the effect of telmisartan on blood pressure.

Amlodipine Amlodipine is a dihydropyridine calcium channel blocker that inhibits the transmembrane influx of calcium ions into vascular smooth muscle and cardiac muscle. Experimental data suggest that 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. Negative inotropic effects can be detected in vitro but such effects have not been seen in intact animals at therapeutic doses. Serum calcium concentration is not affected by amlodipine. Within the physiologic pH range, amlodipine is an ionized compound (pK_a=8.6), and its kinetic interaction with the calcium channel receptor is characterized by a gradual rate of association and dissociation with the receptor binding site, resulting in a gradual onset of effect. Amlodipine is a peripheral arterial vasodilator that acts directly on vascular smooth muscle to cause a reduction in peripheral vascular resistance and reduction in blood pressure.

INDICATIONS: It is indicated for the treatment of essential hypertension.

DOSAGE AND ADMINISTRATION: Telmisartan is an effective treatment of hypertension in once daily doses of 20 to 80 mg while amlodipine is effective in doses of 2.5 to 10 mg. Dosage must be individualized and may be increased after at least 2 weeks. Most of the antihypertensive effect is apparent within 2 weeks and maximal reduction is generally attained after 4 weeks. The maximum recommended dose of telmisartan and amlodipine tablets is 80/10 mg once daily.

CONTRAINDICATION: Telmisartan and amlodipine tablets are contraindicated in patients with known hypersensitivity (e.g., anaphylaxis or angioedema) to telmisartan, amlodipine, or any other component of this product. Do not co-administer aliskiren with telmisartan and amlodipine tablets in patients with diabetes.

WARNINGS & PRECAUTIONS: Fetal toxicity, Hypotension, Hyperkalemia, Patient with impaired hepatic function, renal function impairment, dual blockade of the renin angiotensin aldosterone system, risk of myocardial infraction or increased angina, heart failure.

DRUG INTERACTIONS: Do not co-administer aliskiren with telmisartan and amlodipine tablets in patients with diabetes. Avoid use of aliskiren with telmisartan and amlodipine tablets in patients with renal impairment (GFR <60 mL/min. Reversible increases in serum lithium concentrations and toxicity have been reported during concomitant administration of lithium with angiotensin II receptor antagonists including telmisartan. Therefore, monitor serum lithium levels during concomitant use.

ADVERSE REACTIONS: Impotence, increased sweating, flushing, Allergy, fever, leg pain, malaise, Palpitation, dependent edema, angina pectoris, tachycardia, leg edema, abnormal ECG, Insomnia, somnolence, migraine, vertigo, paresthesia, involuntary muscle contractions, hypoesthesia, Insomnia, somnolence, migraine, vertigo, paresthesia, involuntary muscle contractions, hypoesthesia, Gout, hypercholesterolemia, diabetes mellitus, Arthritis, arthralgia, leg cramps, Anxiety, depression, nervousness, Infection, fungal infection, abscess, otitis media, Asthma, bronchitis, rhinitis, dyspnea, epistaxis, Dermatitis, rash, eczema, pruritus, Micturition frequency, cystitis, Cerebrovascular disorder, Abnormal vision, conjunctivitis, tinnitus, earache. Leukopenia, purpura, thrombocytopenia. Micturition frequency, micturition disorder, nocturia, Sexual dysfunction (male** and female), insomnia, nervousness, depression, abnormal dreams, anxiety, depersonalization, mood change.

MARKETED BY:

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Torrent Pharmaceuticals Limited.

IN/TELSAR AM 80 /TELDAY 80 AM, 80/5mg/MAR 2026/03/ABPI

(Additional information is available on request)