

TELSAR CHM

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

Abbreviated Prescribing information for TELSAR CHM

(Telmisartan, Chlorthalidone and Metoprolol ER Tablets) [Please refer the complete prescribing information for details].

PHARMACOLOGICAL PROPERTIES:

Mechanism of Action: *Telmisartan:* 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. Telmisartan has much greater affinity (more than 3000-fold) for the AT1 receptor than for the AT2 receptor. Telmisartan does not inhibit the angiotensin converting enzyme [ACE (kininase II)]; hence, it does not affect the response to bradykinin. 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. Plasma concentration of angiotensin II and plasma renin activity (PRA) increased in a dose-dependent manner after a single administration of telmisartan to healthy subjects and repeated administration to hypertensive patients. The once-daily administration of up to 80 mg telmisartan to healthy subjects did not influence plasma aldosterone concentrations. In multiple-dose studies with hypertensive patients, there were no clinically significant changes in electrolytes (serum potassium or sodium), or in metabolic function (including serum levels of cholesterol, triglycerides, HDL, LDL, glucose, or uric acid). ***Chlorthalidone:*** Chlorthalidone produces diuresis with increased excretion of sodium and chloride. The site of action appears to be the distal convoluted tubule and connecting segment of the nephron (and perhaps the early cortical collecting tubule). The diuretic effects of chlorthalidone lead to decreased extracellular fluid volume, plasma volume, cardiac output, total exchangeable sodium, glomerular filtration rate, and renal plasma flow. Although the mechanism of action of chlorthalidone and related drugs is not wholly clear, sodium and water depletion appear to provide a basis for its antihypertensive effect. ***Metoprolol:*** Metoprolol is a beta-1 selective beta blocker. It has a relatively greater blocking effect on beta receptors (i.e. those mediating adrenergic stimulation of heart rate and contractility and release of the fatty acids from fat stores) than on beta receptors which are chiefly involved in broncho and vasodilation. Metoprolol only exhibits insignificant membrane stabilising effect and has no agonist effect. Metoprolol reduces or blocks the stimulating effect of catecholamines (particularly released in case of physical or mental stress) on the heart. Metoprolol reduces tachycardia, decreases the cardiac output and the contractility, and lowers the blood pressure.

INDICATIONS: For the treatment of essential hypertension with stable coronary artery disease.

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

CONTRAINDICATION: TELSAR CHM is contraindicated in patients with known hypersensitivity (e.g., anaphylaxis, angioedema or pulmonary oedema) to telmisartan, chlorthalidone, metoprolol or any other component of this product. Because of the chlorthalidone component, this product is contraindicated in patients with anuria or hypersensitivity to other sulfonamide-derived drugs. Do not co-administer aliskiren with TELSAR CHM in patients with diabetes.

WARNINGS & PRECAUTIONS: *Telmisartan:* *Fetal Toxicity, Pregnancy Category D* Use of drugs that act on the renin-angiotensin system during the second and third trimesters of pregnancy reduces fetal renal function and increases fetal and neonatal morbidity and death. Resulting oligohydramnios can be associated with fetal lung hypoplasia and skeletal deformations. Potential neonatal adverse effects include skull hypoplasia, anuria, hypotension, renal failure, and death. When pregnancy is

detected, discontinue Telmisartan as soon as possible. **Chlorthalidone: Fetal Toxicity** Thiazides cross the placental barrier and appear in cord blood. Adverse reactions include fetal or neonatal jaundice and thrombocytopenia. **Impaired Renal Function** In patients with renal disease, chlorthalidone may precipitate azotemia. If progressive renal impairment becomes evident, as indicated by increased blood urea nitrogen, consider withholding or discontinuing diuretic therapy. **Metoprolol:** Beta blockers must be administered with caution to asthmatics. If an asthmatic uses a beta-2 agonist (as tablets or by inhalation) when initiating metoprolol treatment, the dose of the beta-2 agonist must be controlled and increased if necessary.

DRUG INTERACTIONS: Telmisartan: Aliskiren: Do not co-administer aliskiren with Telmisartan in patients with diabetes. Avoid use of aliskiren with Telmisartan in patients with renal impairment (GFR <60 mL/min). **Chlorthalidone: Antidiabetic Drugs (Oral Agents and Insulin):** Dosage adjustment of the antidiabetic drug may be required. **Metoprolol: Barbituric acid derivatives** Barbiturates (studied for pentobarbital) induce the metabolism of metoprolol through enzyme induction.

ADVERSE REACTIONS: Telmisartan: Hypertension, Back pain, nausea, diarrhea, insomnia, dizziness. **Chlorthalidone:** anorexia, gastric irritation, headache, photosensitivity, rash, hyperglycemia, **Metoprolol:** Dizziness, headache, nausea, abdominal pain, diarrhoea, constipation, functional dyspnea.

MARKETED BY:



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IN/TELSAR CHM 40/12.5/25, 40/12.5/50mg /DEC-21/01/PI

(Additional information is available on request)