TELSAR CH

For the use of a Registered Medical Practitioner or Hospital or a Laboratory only.

Abbreviated Prescribing information for TELSAR CH (Telmisartan 40 mg and Chlorthalidone 12.5 mg Tablets)

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

PHARMACOLOGICAL PROPERTIES:

Mechanism of action: The two drugs target two separate mechanisms involved in blood pressure regulation and hence may provide additive blood pressure reduction. 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. Chlorthalidone act primarily on the distal renal tubule (early convoluted part), inhibiting Na⁺ CL⁻ reabsorption (by antagonizing the Na⁺ CL⁻ cotransporter) and promoting Ca⁺⁺ reabsorption.

INDICATIONS: TELSAR CH is indicated for the treatment of hypertension, to lower blood pressure:

• In patients not adequately controlled with monotherapy

• As initial therapy in patients likely to need multiple drugs to help achieve blood pressure goals.

DOSAGE AND ADMINISTRATION: As directed by physician.

CONTRAINDICATION: It is contraindicated in patients with known hypersensitivity (e.g., anaphylaxis or angioedema) to telmisartan, chlorthalidone, 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 CH in patients with diabetes.

WARNINGS & PRECAUTIONS:

FETAL TOXICITY: 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. **Telmisartan:** Fetal Toxicity Pregnancy Category D, Hypotension, Hyperkalemia, Impaired Hepatic Function, Impaired Renal Function, Dual Blockade of the Renin-Angiotensin-Aldosterone System, **Chlorthalidone:** Fetal Toxicity, Impaired Renal Function, Hypokalemia, Hyperuricemia.

DRUG INTERACTION: Telmisartan: Aliskiren, Digoxin, Lithium, Non-Steroidal Anti-Inflammatory Agents including Selective Cyclooxygenase-2 Inhibitors (COX-2 Inhibitors), Ramipril and Ramiprilat. **Chlorthalidone:** Antidiabetic Drugs (Oral Agents and Insulin, Other Antihypertensive Drugs, Pressor Amines (eg, Norepinephrine), Skeletal Muscle Relaxants, NonDepolarizing (eg, Tubocurarine): Possible increased responsiveness to the muscle relaxant.

ADVERSE REACTIONS: Weakness, feel light-headed or dizzy or have difficulty breathing, as these may be signs of a serious allergic (anaphylactic) reaction, gastrointestinal disturbances, nausea, vomiting, or diarrhoea, muscle Pain, dizziness, insomnia, somnolence, anxiety, nervousness, paraesthesia, vertigo, asthma, cough, epistaxis, rhinitis, bronchitis, dyspnoea, sinusitis, urticaria, rash, pruritus non-application site, dermatitis, , drug eruption, photosensitivity, Lyell's syndrome (toxic epidermal necrolysis), Fungal infection, abscess, otitis media, Respiratory tract infection, urinary tract infection.

MARKETED BY:

TORRENT PHARMACEUTICALS LTD. IN/TELSAR CH 40/12.5/Aug-23/01/ABPI (Additional information is available on request)