LEFRA

To be sold by retail on the prescription of a Rheumatologist only

Abbreviated Prescribing information for LEFRA (Leflunomide 10mg and 20mg tablets) [Please refer the complete prescribing information available at www.torrentpharma.com]

PHARMACOLOGICAL PROPERTIES: Leflunomide is an isoxazole immunomodulatory agent which inhibits dihydroorotate dehydrogenase and has antiproliferative activity.

INDICATION: It is indicated for the treatment of active psoriatic arthritis in adults only and active rheumatoid arthritis in adults only.

DOSAGE AND ADMINISTRATION: The recommended dosage of leflunomide is 20 mg once daily. Treatment may be initiated with or without a loading dose, depending upon the patient's risk of leflunomide associated hepatotoxicity and leflunomide-associated myelosuppression. The loading dosage provides steady-state concentrations more rapidly.

CONTRAINDICATION: Pregnant women. Leflunomide may cause fetal harm. If a woman becomes pregnant while taking this drug, stop leflunomide, apprise the patient of the potential hazard to the fetus, and begin a drug elimination procedure, Patients with severe hepatic impairment., Patients with known hypersensitivity to leflunomide or any of the other components of leflunomide. Known reactions include anaphylaxis, Patients being treated with teriflunomide.

WARNINGS & PRECAUTIONS: Caution is advised in patients with hepatotoxicity, Embryo-Fetal Toxicity, known hypersensitivity, immunosuppression potential/bone marrow suppression, skin reactions, malignancy and peripheral neuropathy, need for drug elimination, interstitial lung disease, tuberculosis reactivation, renal insufficiency, Immunosuppression, Bone Marrow Suppression, and Risk of Serious Infections, vaccinations. Blood pressure monitoring should be done before start of leflunomide treatment and periodically thereafter, Stevens - Johnson syndrome, Toxic Epidermal Necrolysis, and Drug Reactions with Eosinophilia and Systemic Symptoms,

DRUG INTERACTION: Cholestyramine and charcoal, hepatotoxic drugs, NSAIDs, tolbutamide, rifampin and warfarin, pioglitazone, duloxetine, ketoprofen, furosemide, atorvastatin,

ADVERSE REACTIONS: Hepatotoxicity, Immunosuppression, Bone marrow suppression, Stevens-Johnson syndrome and toxic epidermal necrolysis, Peripheral neuropathy, Interstitial lung disease, agranulocytosis, leukopenia, neutropenia, severe infections including sepsis, angioedema, erythema multiforme.

MARKETED BY:

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IN/LEFRA 10 mg, 20 mg/FEB-2024/04/ABPI

(Additional information is available on request)