LEFRA

For the use of a Rheumatologist Only 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: In adults for the treatment of active Rheumatoid Arthritis (RA) to reduce signs and symptoms, and to retard structural damage as evidenced by X-ray erosions and joint space narrowing.

DOSAGE AND ADMINISTRATION: It is recommended that leflunomide therapy be initiated with a loading dose of one 100 mg tablet per day for 3 days. Daily dosing of 20 mg is recommended for treatment of patients with RA. Hematology parameters and liver enzymes should be monitored.

CONTRAINDICATION: Contraindicated in pregnant women, or women of childbearing potential who are not using reliable contraception, patients with known hypersensitivity to leflunomide, teriflunomide, or any of the other components of leflunomide.

WARNINGS & PRECAUTIONS: Caution is advised in patients with hepatotoxicity, known hypersensitivity, immunosuppression potential/bone marrow suppression, skin reactions, malignancy and peripheral neuropathy, need for drug elimination, interstitial lung disease, tuberculosis reactivation, renal insufficiency, vaccinations. Blood pressure monitoring should be done before start of leflunomide treatment and periodically thereafter.

DRUG INTERACTION: Cholestyramine and charcoal, hepatotoxic drugs, NSAIDs, tolbutamide, rifampin and warfarin.

ADVERSE REACTIONS: Allergic reaction, asthenia, flu syndrome, infection, upper respiratory, injury accident, pain, abdominal pain, back pain, hypertension, new onset of hypertension, chest pain, anorexia, diarrhea, dyspepsia, gastroenteritis, abnormal liver enzymes, nausea, GI/abdominal pain, mouth ulcer, vomiting, hypokalemia, weight loss, arthralgia, leg cramps, joint disorder, synovitis, tenosynovitis, dizziness, headache, paresthesia, bronchitis, increased cough, respiratory infection, pharyngitis, pneumonia, rhinitis, sinusitis, alopecia, eczema, pruritus, rash, dry skin and urinary tract infection.

MARKETED BY:



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IN/LEFRA/FEB 2015/01/AbPI

(Additional information is available on request)