For the use only of a Registered Medical Practitioner (Rheumatologists) or a Hospital or a Laboratory

Abridged Prescribing Information

LEFLUNOMIDE TABLETS IP
ARAVA®

Composition : Each tablet contains 10mg, 20mg of Leflunomide IP.

Therapeutic Indications : Treatment of active rheumatoid arthritis and treatment of active psoriatic arthritis in adults only.

Dosage & Administration: Loading dose of 100mg once daily for 3 days. Recommended maintenance dose is 20 mg leflunomide once daily. Not recommended in patients less than 18 years of age. No dosage adjustment is required in elderly.

Contraindications : Patients with hypersensitivity to leflunomide, teriflunomide or to any of the excipients; pregnant women or women of childbearing potential who are not using reliable contraception. Pregnancy must be excluded before start of treatment with leflunomide.

Precautions : *General* - Due to prolonged half life of active metabolite (A771726), adverse reactions may occur or persist even after leflunomide administration has been discontinued. If a severe adverse reaction occurs, or if A771726 needs to be cleared rapidly form the body cholestyramine or activated charcoal has to be initiated. Co-administration of teriflunomide with leflunomide is not recommended, as leflunomide is the parent compound of teriflunomide.

Liver – Use with caution in patients with impaired liver function. Not recommended in patients with significant hepatic impairment or pre-existing hepatic disease. SGPT must be checked before start of treatment and at least at monthly intervals during the first 6 months, then every 6-8 weeks thereafter. Rare cases of serious liver injury in isolated cases with fatal outcome have been reported during treatment with leflunomide.

Haematopoetic and immune system – In patients with pre-existing anaemia, leucopenia and / or thrombocytopenia as well as in patients with impaired bone marrow function or those at risk of bone marrow suppression, the risk for occurrence of haematological reactions is increased. Complete blood cell count, including differential white blood cell count and platelets should be performed before starting leflunomide treatment as well as monthly for the first 6 months of treatment and every 6-8 weeks thereafter. Leflunomide is not recommended in patients with severe immunodeficiency (eg AIDS), significant impairment of bone marrow function, serious infection.

Infections – Immunosuppression potential may cause patients to be more susceptible to infections.

Respiratory – Interstitial lung disease has been reported rarely.

Peripheral Neuropathy – Cases of peripheral neuropathy have been reported in patients receivingleflunomide . Consider discontinuation and perform drug elimination procedure.

Renal Impairment - Caution in patients with renal impairment.

Skin reactions- Cases of Stevens-Johnson syndrome, toxic epidermal necrolysis and drug reaction with eosinophilia and systemic symptoms (DRESS) have been reported in patients treated with leflunomide. If the patient taking leflunomide develop any of these skin conditions, therapy should be stopped and washout procedures should be initiated immediately.

Blood pressure – BP should be checked before start of leflunomide and periodically thereafter.

Use in males – Men wishing to father a child should consider discontinuing leflunomide and go through the drug elimination procedure.

Pregnancy & Lactation : Contraindicated in pregnancy. Women should not breast feed as animal studies indicate passage of leflunomide or its metabolites pass into breast milk.

Adverse Reactions : Common (1-10% of patients) - Diarrhoea, nausea, vomiting, anorexia, oral mucosal disorders, abdominal pain, elevation of liver parameters, colitis including microscopic colitis, increase in blood pressure, leucopenia with leucocyte count > 2 x 10^9/l (> 2 G/l), headache, dizziness, paraesthesia, mild allergic reactions, pruritus, eczema, dry skin, increased hair loss, weight loss, asthenia

For full prescribing information, please contact Sanofi India Limited, Sanofi House, CT Survey No 117-B, L&T Business Park, Saki Vihar Road, Powai, Mumbai 400072

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