For the use only of a Registered Medical Practitioners or a Hospital or a Laboratory

Abridged Prescribing Information

Alemtuzumab Concentrate for solution for infusion **12mg/1.2 ml (10 mg/ml)**

Lemtrada®

COMPOSITION: Each vial contains Alemtuzumab 12 mg in 1.2 ml

THERAPEUTIC INDICATION: Treatment of patients with an aggressive form of Relapsing Remitting Multiple Sclerosis (RRMS) in whom there has been a failure of one first line disease modifying therapy

DOSAGE & ADMINISTRATION: Recommended dose is 12 mg/day administered by IV infusion for 2 or more treatment courses. Initial treatment of 2 courses: First treatment course: 12 mg/day on 5 consecutive days (60 mg total dose). Second treatment course: 12 mg/day on 3 consecutive days (36 mg total dose) administered 12 months after the first treatment course.

SAFETY RELATED INFORMATION

Contraindications: In patients with known Type 1 hypersensitivity or anaphylactic reactions to the active substance or any of the excipients; In patients who are infected with Human Immunodeficiency Virus (HIV).

Pregnancy: Should be administered during pregnancy only if the potential benefit justifies the potential risk to the fetus. Women of child bearing potential should use effective contraceptive measures when receiving treatment with Lemtrada and for 4 months following treatment.

Lactation: Caution should be exercised when Lemtrada is administered to a nursing woman. Breast feeding should be discontinued during each course of treatment with Lemtrada and for 4 months following the last infusion of each treatment course.

Warnings and Precautions for use: Before treatment, patients must receive educational information and be informed about the risks and benefits, and the need to commit to follow up from treatment initiation until 48 months after the last infusion of the second Lemtrada treatment course.. ***Autoimmunity***: Treatment with Lemtrada may result in the formation of autoantibodies and increase the risk of autoimmune mediated conditions including immune thrombocytopenic purpura (ITP), thyroid disorders or, rarely, nephropathies (e.g., anti-glomerular basement membrane disease) and autoimmune hepatitis (AIH) ***Autoimmune Hepatitis (AIH)***: Autoimmune hepatitis causing clinically significant liver injury, including acute liver failure requiring transplant, has been reported in patients treated with LEMTRADA in the postmarketing setting ***Immune Thrombocytopenic Purpura:*** Serious events of ITP have been observed in controlled MS clinical trials. ***Nephropathies:*** Nephropathies, including anti-glomerular basement membrane (anti-GBM) disease have been observed. Serum creatinine levels and urinalysis with cell counts should be obtained prior to initiation of treatment and at monthly intervals thereafter until 48 months after the last infusion. ***Thyroid Disorders***: Observed autoimmune thyroid disorders included hyperthyroidism or hypothyroidism. Thyroid disease pose special risks in women who are pregnant. ***Cytopenias:*** Suspected autoimmune cytopenias such as neutropenia, hemolytic anemia, and pancytopenia have been infrequently reported in patients. CBC results should be used to monitor for cytopenias. ***Infusion Associated Reactions***: It is recommended that patients be pre-medicated with corticosteroids immediately prior to the initiation of Lemtrada on the first 3 days of any treatment course to ameliorate the effects of infusion reactions. ***Infections:*** Infections were predominantly mild to moderate in severity. Infections included nasopharyngitis, urinary tract infection, upper respiratory tract infection, sinusitis, oral herpes, influenza, and bronchitis. Serious infections occurred in 2.7% of Lemtrada patients.

Pneumonitis : Most cases occurred within first month after treatment. Patients should be advised to report symptoms of pneumonitis. ***Acute Acalculous Cholecystitis:*** May increase the risk of acute acalculous cholecystitis. . ***Contraception:*** See Pregnancy ***Vaccines:*** It is recommended that patients have completed local immunization requirements at least 6 weeks prior to treatment with Lemtrada. Live vaccines should not be administered to patients who have been recently treated.

ADVERSE REACTIONS:

Post- Marketing Experience with Lemtrada: Nervous System Disorders: Stroke, including hemorrhagic and ischemic stroke, and cervicocephalic arterial dissection. Gastrointestinal System Disorders: Cases of cholecystitis have been reported. Infection and Infestations :Cytomegalovirus infections have been reported with concomitant corticosteroid use. Respiratory Thoracic and Mediastinal Disorders : Pulmonary alveolar hemorrhage. Blood and lymphatic system disorders: Haemophagocytic lymphohistiocytosis, Cardiac disorders: Transient myocardial ischemia as an infusion associated reaction, Hepatobiliary Disorders: Autoimmune hepatitis

For full prescribing information please contact: Sanofi-Synthelabo India Private Ltd, Sanofi House, CTS No. 117-B, L&T Business Park, Saki Vihar Road, Powai 400072

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