LEMTRADA® alemtuzumab 12mg/1ml

LEMTRADA® ▼ (alemtuzumab)

Healthcare professional checklist – IE

Alemtuzumab is indicated as a single disease modifying therapy in adults with highly active relapsing remitting multiple sclerosis (RRMS) for the following patient groups:

- Patients with highly active disease despite a full and adequate course of treatment with at least one disease modifying therapy (DMT) or
- Patients with rapidly evolving severe RRMS defined by 2 or more disabling relapses in one year, and with 1 or more Gadolinium enhancing lesions on brain magnetic resonance imaging (MRI) or a significant increase in T2 lesion load as compared to a previous recent MRI.

Timing	Activity		Detail
Initial patient screening	Contraindications	☐	Assess patient to ensure they don't hold any of the following contraindications: • Hypersensitivity to alemtuzumab or to any of the excipients listed in Summary of Product Characteristics (SmPC) section 6.1 • Human Immunodeficiency Virus (HIV) infection • Severe active infections until complete resolution • Uncontrolled hypertension • History of arterial dissection of the cervicocephalic arteries • History of stroke • History of angina pectoris or myocardial infarction • Known coagulopathy, on anti-platelet or anti-coagulant therapy • Other concomitant autoimmune diseases besides multiple sclerosis (MS)
	Precautions for use	☐	Consider combined effects on the patient's immune system if alemtuzumab is used concomitantly with antineoplastic or immunosuppressive therapies
	Recommended screening	☐ ☐ ☐ ☐ ☐	Evaluate for active and inactive ("latent") tuberculosis (as per local guidelines) Evaluate MRI scan for any sign suggestive for Progressive Multifocal Leukoencephalopathy (PML) prior to initiation and readministration of alemtuzumab treatment Consider screening patients at high risk of hepatitis B virus (HBV) and/or hepatitis C virus (HCV) infection. Exercise caution in prescribing alemtuzumab to patients identified as carriers of HBV and/or HCV Consider screening for Human Papillomavirus (HPV) in female patients prior to treatment and annually thereafter Consider evaluation of cytomegalovirus (CMV) immune serostatus (as per local guidelines)
	Baseline lab tests and measurements	☐ ☐ ☐ ☐ ☐	Obtain baseline electrocardiogram (ECG) and vital signs, including heart rate and blood pressure (BP) measurements Full blood count with differential Test serum transaminases and serum creatinine levels Perform thyroid function tests, such as thyroid stimulating hormone (TSH) level Perform urinalysis with microscopy
	Understanding of benefits and risks	☐	Ensure the patient has been informed about and understands the potential safety events associated with alemtuzumab (including serious autoimmune disorders, infections and malignancies), the monitoring requirement and the measures to minimise risk (e.g. watching for symptoms, carrying the Patient Alert Card and the need to commit to periodic monitoring for at least 48 months after the last treatment)
6 weeks prior to treatment, if needed	Vaccinations	☐ ☐	Recommend that patients complete local immunisation requirements Consider varicella zoster virus vaccination of antibody negative patients before initiating a course of alemtuzumab treatment
2 weeks prior to, during, and for at least 1 month after treatment	Diet	☐	Recommend that patients avoid ingestion of uncooked or undercooked meats, soft cheeses and unpasteurised dairy products 2 weeks prior to, during, and for at least 1 month after treatment

HPRA approval date: December 2022. Date of review: December 2022. Job code: MAT-IE-2200594 (v1.0)

Timing	Activity		Detail
Immediately prior to treatment	General health	☐	Delay initiation of alemtuzumab administration in patients with severe active infection until the infection is completely resolved
	Pretreatment for infusion-associated reactions	☐ ☐	Pretreat with corticosteroids immediately prior to alemtuzumab infusion on each of the first 3 days of any treatment course Pretreat with antihistamines and/or antipyretics prior to alemtuzumab administration may also be considered
	Oral prophylaxis for herpes	☐	Administer 200 mg aciclovir (or equivalent) twice a day from first day of treatment and continuing for a minimum of 1 month following treatment with alemtuzumab
	Pregnancy and contraception	☐	Ensure women of childbearing potential use effective contraceptive measures when receiving a course of treatment with alemtuzumab and for 4 months following the course of treatment
Infusion administration	Pre-infusion evaluations	☐ ☐	Obtain a baseline ECG and vital signs, including heart rate and BP measurements Perform laboratory tests (full blood count with differential, serum transaminases, serum creatinine, thyroid function test and urinalysis with microscopy)
	During infusion	☐ ☐	Monitor heart rate, BP, and overall clinical status of the patient at least once every hour Discontinue the infusion: • in the case of a severe adverse event • if the patient shows clinical symptoms suggesting development of a serious adverse event associated with the infusion (myocardial ischaemia, haemorrhagic stroke, cervicocephalic arterial dissection or pulmonary alveolar haemorrhage)
	Post-infusion	☐ ☐ ☐ ☐	Flush lines to ensure the entire dosage has been administered to the patient Observe patients for a minimum of 2 hours after each infusion. Patients displaying clinical symptoms that may indicate a serious adverse event should be closely monitored until complete resolution of the symptoms and observation time extended as appropriate Educate patients about the potential for a delayed onset of infusion-associated reactions and instruct them to report symptoms immediately and seek appropriate medical care if they arise Obtain a platelet count on Days 3 and 5 of the first infusion course, and after infusion on Day 3 of any subsequent course. Follow clinically significant thrombocytopenia until resolution and consider referral to a haematologist for management
For at least 48 months after last treatment	Monitoring activities	☐ ☐ ☐ ☐	Full blood count with differential and serum creatinine: monthly Perform urinalysis with microscopy: monthly Perform thyroid function tests: every 3 months Perform liver function testing: monthly

Patient's name: .....

Patient's medical record number: .....

Patient's date of birth: .....

Prescriber's name: .....

Date: .....

If you have any enquiries or wish to request extra hard copies of any of these materials please contact Sanofi Medical Information: Telephone: 01 403 5600; Email: IEmedinfo@sanofi.com

Additionally, electronic versions of these materials are available to download on the following website; https://www.hpra.ie/homepage/medicines/safety-information/educational-material

▼Lemtrada (alemtuzumab) is subject to additional monitoring. This will allow quick identification of new safety information.Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via contacting HPRA Pharmacovigilance, website: www.hpra.ie. Side effects should also be reported to Sanofi: Tel: 01 403 5600 e-mail: IEPharmacovigilance@sanofi.com

SANOFI GENZYME

HPRA approval date: December 2022. Date of review: December 2022. Job code: MAT-IE-2200594 (v1.0)