LEMTRADA® (alemtuzumab)
Healthcare professional checklist

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 LEMTRADA 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 of 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 LEMTRADA 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
		☐	Complete 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 LEMTRADA (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 LEMTRADA 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

Timing	Activity		Detail
Immediately prior to treatment	General health	☐	Delay initiation of LEMTRADA administration in patients with severe active infection until the infection is fully controlled
	Pretreatment for infusion-associated reactions	☐ ☐	Pretreat with corticosteroids immediately prior to LEMTRADA infusion on each of the first 3 days of any treatment course Pretreat with antihistamines and/or antipyretics prior to LEMTRADA 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 LEMTRADA
	Pregnancy and contraception	☐	Ensure women of childbearing potential use effective contraceptive measures when receiving a course of treatment with LEMTRADA 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 (complete 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	☐ ☐ ☐ ☐	Complete 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 name: .....

Patient medical record number: .....

Patient date of birth: .....

Prescriber name: .....

Date: .....

Adverse events should be reported. Reporting forms and information can be found at http://www.medicinesauthority.gov.mt/adrportalAlternatively adverse events can be reported to Sanofi S.r.l. atPharmacovigilanceMalta@sanofi.com

Approved by Medicine Authority on 03 Nov 2022

LEMTRADA® alemtuzumab 12mg IV

sanofi