LEMTRADA® (alemtuzumab)
Healthcare professional checklist

Use this checklist together with the LEMTRADA® Healthcare Professional's Guide. For full prescribing details please refer to the Professional Information (PI) approved by the medicines regulatory authority.

For Medical Information Enquiries, kindly contact ZA.Medinfo@sanofi.com
To report an adverse event:
- Use the Med Safety App (accessible from the Apple store (for iOS devices) and Google Play (for android devices)) via https://medsafety.sahpra.org.za/ **alternatively,**
- Complete the ADR reporting form accessible via the SAHPRA website at www.sahpra.org.za and email it to adr@sahpra.org.za **and**
- Adverse events should also be reported to the Pharmacovigilance Department of Sanofi by emailing za.drugsafety@sanofi.com or calling 011 256 3700

Timing	Activity		Detail
Initial patient screening	Contraindications	☐	Assess patient to ensure they don't have any of the following contraindications: • Hypersensitivity to alemtuzumab or to any of the excipients listed in the Professional Information (PI) section 6.1 • Human Immunodeficiency Virus (HIV) infection • Severe active infection • Uncontrolled hypertension • History of arterial dissection of the cervicocephalic arteries • History of stroke • History of angina pectoris or myocardial infarction • Known coagulopathy or on concomitant anticoagulant therapy
	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 and, if required, prescribe appropriate treatment if the patient has active tuberculosis, or appropriate prophylactic treatment to prevent tuberculosis infection, if the patient presents with latent tuberculosis, according to the relevant South African guidelines, prior to initiation of LEMTRADA® treatment
		☐	Evaluate MRI scan for any sign suggestive for PML prior to initiation and readministration of LEMTRADA® 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)
		☐	Exclude pregnancy in woman of child bearing potential
	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)
		☐	Has patient materials (LEMTRADA® Patient Guide and Patient Alert card) been given to the patient at the time of prescription, prior to treatment initiation. If not, provide patient with materials as soon as possible and review on a regular basis at follow up visits
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 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 Pretreatment with antihistamines and/or antipyretics prior to LEMTRADA® administration may also be considered
	Oral prophylaxis for herpes	☐	Prophylaxis with an oral anti-herpes medicine should be initiated starting on the first day of LEMTRADA® treatment and continued for a minimum of 1 month following each course of treatment with LEMTRADA®
	Pregnancy and contraception	☐	LEMTRADA® should not be administered in pregnancy. 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
During treatment, between courses and 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
During treatment, between courses, and post-treatment	Monitoring for tuberculosis	☐	Continuously monitor for active and inactive ("Latent") tuberculosis infection based on individual patient and treatment risk factors, and if required, prescribe appropriate treatment if the patient has active tuberculosis or appropriate prophylactic treatment to prevent tuberculosis infection if the patient presents with latent tuberculosis, according to the relevant South African guidelines prior to re-administration of LEMTRADA® treatment

Patient name: .....

Patient medical record number: .....

Patient date of birth: .....

Prescriber name: .....

Date: .....

For full prescribing information refer to the professional information approved by the medicines regulatory authority.

S4 **LEMTRADA®** (Concentrate for solution for infusion) **COMPOSITION:** Each vial contains 12 mg/1,2 mL alemtuzumab (10 mg/mL). **REGISTRATION NUMBER:** 48/30.1/0263.
NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION: sanofi-aventis south africa (pty) ltd, Reg. No. 1996/010381/07, Floor 5, Building I, Hertford Office Park, 90 Bekker Road, Midrand, 2196. Tel: 011 256 3700.

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LEMTRADA® alemtuzumab 12mg IV

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