LEMTRADA® (alemtuzumab)
healthcare professional checklist

Patient name: .....

Patient medical record number: .....

Patient date of birth: .....

Prescriber name: .....

Date: .....

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 of this medicinal product as listed in section 6.1 of the SmPC.
		☐	Infection with human immunodeficiency virus (HIV)
		☐	Presence of severe active infections until fully resolved
		☐	Uncontrolled hypertension
		☐	History of cerebrovascular and cardiovascular disorders, including arterial dissection of the cervicocephalic arteries, stroke, angina pectoris or myocardial infarction.
		☐	Patients with known coagulopathies or receiving anti-platelet or anti-coagulant therapy
		☐	Presence of other concomitant autoimmune diseases, apart from multiple sclerosis (MS)
	Precautions for use	☐	Consider the increased risk of immunosuppression associated with any concomitant use of antineoplastic or immunosuppressive treatments.
	Recommended screening	☐	Patients should be evaluated for both active and latent tuberculosis according to local guidelines before starting treatment
		☐	An MRI scan should be performed prior to initiation and prior to re-administration of alemtuzumab to assess for signs suggestive of PML

		☐	Patients at high risk of HBV and/or HCV infection should be screened prior to treatment. Caution is advised when prescribing LEMTRADA to patients who are carriers of HBV and/or HCV
		☐	Female patients should undergo screening for HPV prior to treatment initiation and annually thereafter, in line with standard of care.
		☐	Consider evaluation of cytomegalovirus (CMV) immune serostatus (as per local guidelines)
	Baseline lab tests and measurements	☐	Baseline electrocardiogram (ECG) and vital signs (including heart rate and blood pressure) should be obtained.
		☐	Complete blood count (CBC) with differential should be performed.
		☐	Serum transaminases and serum creatinine should be tested to assess liver and renal function.
		☐	Thyroid function should be assessed, including measurement of thyroid stimulating hormone (TSH).
		☐	Urinalysis with microscopy should be performed.
		☐	Evaluate serum creatinine tests.
	Understanding of benefits and risks	☐	Patients should be fully informed of, and should understand, the potential safety risks associated with LEMTRADA (including serious autoimmune disorders, infections, and malignancies), the required monitoring program, and the risk-minimization measures (e.g. vigilance for symptoms, carrying the Patient Alert Card, and compliance with **regular monitoring for at least 48 months after the last infusion).**

6 weeks prior to treatment, if needed	Vaccinations	☐ ☐ ☐	Patients should complete all immunizations according to local guidelines prior to initiating LEMTRADA. Patients without a confirmed history of varicella (chickenpox) or without documented VZV antibodies should be vaccinated prior to initiating LEMTRADA. Vaccination should be administered at least 6 weeks prior to treatment.
2 weeks prior to, during, and for at least 1 month after treatment	Diet	☐	Patients should be advised to avoid raw or undercooked meats, soft cheeses, and unpasteurized dairy products for at least 2 weeks prior to treatment, during treatment, and for at least 1 month after each course of LEMTRADA.
Immediately prior to treatment	General health	☐ ☐	LEMTRADA treatment should be delayed in patients with severe active infection until the infection is adequately controlled. 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.
	Pretreatment for infusion-associated reactions	☐ ☐	Pretreatment with corticosteroids is recommended 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	☐	Administer aciclovir 200 mg (or an equivalent antiviral) twice daily, starting on the first day of each treatment course and continuing for at least 1 month following completion of treatment with LEMTRADA..
	Pregnancy and contraception	☐	Women of childbearing potential must use effective contraceptive measures during treatment with LEMTRADA and for at least 4 months after completion of each treatment course.

Infusion administration	Pre-infusion evaluations	☐	Obtain baseline ECG and record vital signs, including heart rate and blood pressure (BP) measurements.
		☐	Perform laboratory tests: complete blood count with differential, serum transaminases, serum creatinine, thyroid function tests (including TSH), and urinalysis with microscopy.
	During infusion	☐	Monitor heart rate, blood pressure (BP), and overall clinical status of the patient at least once every hour during infusion.
		☐	Discontinue the infusion: • in 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 the intravenous line with saline after infusion to ensure the entire prescribed dose of LEMTRADA has been delivered.
		☐	Observe patients for at least 2 hours after each infusion. Extend the observation period and provide appropriate supportive care if clinical signs or symptoms suggestive of a serious adverse event occur.
		☐	Educate patients that infusion-associated reactions may occur during infusion or may be delayed for several days. Instruct them to report symptoms immediately and seek urgent medical care.
		☐	Monitor platelet counts: Obtain platelet counts on Day 3 and Day 5 of the first treatment course, and on Day 3 of each subsequent treatment course. If clinically significant thrombocytopenia is detected, monitor closely until resolution and consider referral to a hematologist for further management.

For at least 48 months after last treatment	Monitoring activities	☐ ☐ ☐ ☐ ☐	Complete blood count (CBC) with differential: perform monthly Serum creatinine: perform monthly Urinalysis with microscopy: perform monthly Thyroid function tests (TSH, with reflex to free T4 if abnormal): perform every 3 months Liver function tests (serum transaminases and bilirubin): perform monthly

In case of any drug related adverse events, please contact:

The National Pharmacovigilance Centre (NPC- Saudi Food and Drug Authority (SFDA))

Call Center: 19999

E-mail: npc.drug@sfda.gov.sa

Website: https://ade.sfda.gov.sa

For SANOFI Pharmacovigilance center, please contact:+966-544-284-797 or

E-mail: Ksa_pharmacovigilance@sanofi.com