Please carry this card with you at all times and show it to all emergency and healthcare providers involved in your care to inform them about your treatment with LEMTRADA®.

I have been treated with LEMTRADA®, a treatment for multiple sclerosis (MS), which affects the immune system. I am participating in a special monitoring programme which continues for at least 48 months after my last treatment.

LEMTRADA® should not be administered during pregnancy. Woman who are of child-bearing potential should use effective contraceptive methods during each treatment course with LEMTRADA® and for 4 months after each course of treatment. If you become pregnant consult your doctor immediately. Breastfeeding is not recommended during each treatment course and for 4 months after each course of treatment.

LEMTRADA® treatment may increase the risk of:

- Serious infections
- Tuberculosis:
  - Your doctor will screen for active and inactive ("latent") tuberculosis prior to starting, between courses, as well as after LEMTRADA® treatment
  - If required, your doctor may prescribe appropriate treatment to treat an active tuberculosis infection, or prophylactic treatment to prevent tuberculosis infection if you present with latent tuberculosis, according to the relevant South African guidelines
  - If you display symptoms of tuberculosis (e.g. shortness of breath, cough, wheezing, chest pain or tightness, night sweats, and coughing up blood) or you have been in contact with someone who has tuberculosis, please contact your doctor to arrange a screening
- Serious side effects that usually occur within 1 to 3 days of LEMTRADA® infusion: heart attack, stroke, tears in blood vessels supplying the brain, bleeding in the lung, and thrombocytopenia
- Delayed side effects: thyroid disorders, ITP, kidney problems, autoimmune hepatitis, HLH, acquired haemophilia A, cytopenias and TTP

Doctors: See LEMTRADA® Professional Information
Patients: See the LEMTRADA® Patient Information Leaflet

My neurologist prescribing LEMTRADA® can be contacted via phone or email using the details below. Other doctors or healthcare professionals involved in my care may also be listed.

If any medical evaluations are undertaken, please provide copies of all medical records, including any treatments and/or test results, to the doctor(s) and nurse(s) listed below.

Patient name:.....

Patient signature:.....

Date of last LEMTRADA® infusion:.....

	Name	Phone number	Email
Neurologist			
General Practitioner			
MS Nurse			

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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It's very important that you continue to attend your monthly tests, between treatment courses and for at least 48 months (4 years) after your last infusion (even if you are feeling well).

Delayed side effects may occur beyond 48 months. Therefore you must continue to look out for the signs, even after your monthly tests are no longer required.

Early detection and diagnosis may give you the best opportunity for improvement

You must also continue to watch for signs and symptoms

Do this during and between treatment courses and for at least 48 months after your last infusion

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

What you should know about LEMTRADA® (alemtuzumab)
Call your neurologist right away to report these symptoms no matter if they are new, worsening or returning symptoms. Seek medical attention if you cannot reach your own doctor, and make sure you show them this card. **Refer to the LEMTRADA® Patient Information Leaflet and LEMTRADA® Patient Guide for more information.**

IMPORTANT SIDE EFFECTS TO WATCH FOR:

Serious infections
Fever and/or chills, fatigue, feeling unwell
Tuberculosis infection
- Shortness of breath, cough, wheezing, chest pain or tightness, night sweats and coughing up blood

Rare brain infection called PML (progressive multifocal leukoencephalopathy)
- Progressive weakness or clumsiness of limbs
- Disturbance of vision, speech difficulties
- Changes in thinking, memory, and orientation leading to confusion and personality changes

Serious side effects occurring shortly after LEMTRADA® infusion
(Usually occur within 1-3 days of infusion)
Heart attack
- Chest pain or discomfort, shortness of breath, pain or discomfort in arms, jaw, neck, back or stomach
- Feeling dizzy or lightheaded, nausea, sweating

Stroke or tears in blood vessels supplying the brain
- Sudden onset of drooping of parts of the face, weakness on one side, difficulty with speech
- Sudden severe headache, neck pain

Bleeding in the lungs
- Shortness of breath, chest pain or discomfort, coughing up blood

Thrombocytopenia
- Easy bruising and/or bleeding

Delayed side effects (which can occur months to years after infusion)
Thyroid disorders
- Hyperthyroidism (overactive thyroid gland)
  - Excessive sweating, unexplained weight loss, eye swelling, nervousness, fast heartbeat
- Hypothyroidism (underactive thyroid gland)
  - Feeling cold, unexplained weight gain, worsening tiredness or newly occurring constipation

Immune thrombocytopenic purpura (ITP)
- Small scattered spots on your skin that are red, pink or purple, easy bruising, bleeding from a cut that is harder to stop than usual, heavier, longer or more frequent menstrual periods than normal, bleeding between your menstrual periods
- Bleeding from your gums or nose that is new or takes longer than usual to stop, coughing up blood

Kidney problems including anti-Glomerular Basement Membrane disease (anti-GBM disease)
- Blood in the urine which may be red or tea-coloured, swelling in your legs or feet, coughing up blood

Autoimmune hepatitis
- Unexplained nausea, vomiting, fatigue, abdominal pain, loss of appetite, abdominal swelling
- Yellow skin or eyes and/or dark urine, bleeding or bruising more easily than normal

Haemophagocytic lymphohistiocytosis (HLH)
- Unexplained high fever, severe headache, stiff neck, lymph node enlargement, bruising, yellow skin or skin rash

Acquired haemophilia A
- Bleeding from a cut that takes longer than usual to stop
- Spontaneous bruising, nose bleeds, painful or swollen joints
- Unexplained or excessive bleeding after surgery or dental work

Cytopenias
- Low blood cell counts

Thrombotic thrombocytopenic purpura (TTP)
- Bruising under the skin, or in the mouth, that may appear as red pinpoint dots, with or without unexplained extreme tiredness, fever, confusion, speech changes, yellowing of the skin or eyes (jaundice), low amount of urine, dark coloured urine