

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. Please refer to the Patient Information Leaflet (PIL) and Patient Guide for more information.

IMPORTANT SIDE EFFECTS TO WATCH FOR

An Infection called PML (progressive multifocal leukoencephalopathy)

- Progressive weakness or clumsiness of limbs, disturbance of vision, speech difficulties or changes in thinking, memory, and orientation leading to confusion and personality changes

Serious side effects occurring shortly after LEMTRADA infusion

(Usually 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 and tears/dissections 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
- These symptoms may progress over days to weeks

Delayed side effects (can occur months to years after infusion)

Thyroid disorders

Hyperthyroidism

- Excessive sweating, unexplained weight loss, eye swelling, nervousness, fast heartbeat

Hypothyroidism

- Feeling cold, unexplained weight gain, worsening tiredness, newly occurring constipation

Immune thrombocytopenic purpura (ITP)

- Bleeding from your gums or nose that is new or takes longer than usual to stop, coughing up blood
- Small scattered spots on your skin that are red, pink or purple, spontaneous or easy bruising, bleeding from a cut that is harder to stop than usual, heavier, longer or more frequent menstrual periods than normal
- Painful or swollen joints

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 and eyes and/or dark urine, bleeding or bruising more easily than normal

Haemophagocytic lymphohistiocytosis (HLH)

- Unexplained high fever, persistent severe headache, enlarged liver or spleen, stiff neck, lymph node enlargement, yellow skin, skin rash

Acquired haemophilia A

- Bleeding from a cut that takes longer than usual to stop
- Spontaneous bruising, nose bleeds, painful or swollen joints

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

Adult onset still disease (AOSD)

- Fever $>39^{\circ}\text{C}$ or 102.2°F lasting more than 1 week, pain, stiffness with or without swelling in multiple joints and/or a skin rash

Autoimmune encephalitis (AIE)

- Behavioural and/or psychiatric changes, movement disorders, short term memory loss or seizures as well as other symptoms which may resemble an MS relapse

PATIENT ALERT CARD

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 treatment may increase the risk of:

- Serious infections
- Serious side effects that usually occur within 1–3 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, TTP, AOSD and AIE

Doctors:

See LEMTRADA Summary of Product Characteristics (SmPC) Jan 2022 for more information

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			

It's very important that you continue to attend your monthly tests 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 and symptoms, 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 for at least 48 months after your last course of treatment with LEMTRADA

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
E-mail: Ksa_pharmacovigilance@sanofi.com