

What you should know about LEMTRADA® (alemtuzumab)

Important side effects to watch for:

Call your neurologist right away to report these symptoms no matter if they are new, worsening or return symptoms. If you cannot reach your own doctor seek immediate medical attention. Show them this card!

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 or heavier menstrual bleeding
- Bleeding from your gums or nose that is new or takes longer than usual to stop
- Coughing up blood (could also be a sign of kidney problems)

Kidney problems

- Blood in the urine which may be red or tea-coloured
- Swelling in your legs or feet

Serious infections

- Fever and/or chills
- Swollen glands
- Shortness of breath, cough, wheezing, chest pain or tightness and coughing up blood

Call for reporting:

Healthcare professionals should report any adverse events suspected to be associated with the use of Lemtrada to Sanofi Malta Ltd., 3rd Floor, Avantech Building, St. Julian's Road, San Gwann SGN 2805. Tel: 21493022, fax 21493024

Side effects could occur long after you received a course of treatment with LEMTRADA.

It is very important that you continue to have your monthly tests (even if you are feeling well).



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 4 years after your last course of treatment with LEMTRADA.

Alternatively any suspected ADRs and medication errors can be reported to the Medicines Authority. Report forms can be downloaded from www.medicinesauthority.gov.mt/adportal and posted to Medicines Authority Post-licensing Directorate, Sir Temi Zammit Buildings, Malta Life Sciences Park, San Gwann SGN 3000 Malta or sent by email to postlicensing.medicinesauthority@gov.mt

My neurologist prescribing LEMTRADA can be contacted at the number 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) listed below.

Patient name: _____

Patient signature: _____

	Name	Phone Number
Neurologist		
General Practitioner		
MS Nurse		

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Patient Alert Card

Please carry this card with you at all times and show it to all emergency and healthcare providers in order 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 program which continues every month for 4 years after my last treatment.

LEMTRADA treatment may increase the risk of:

- Autoimmune disorders such as:
 - A bleeding problem called Immune Thrombocytopenic Purpura (ITP)
 - Rare kidney problems, such as anti-glomerular basement membrane [anti-GBM] disease
 - Problems of the thyroid gland (hypo/hyper thyroidism)
- Serious infections

Doctors: See SmPC LEMTRADA for more information