

**LEMTRADA** treatment may increase the risk of:

**Autoimmune disorders such as:**

- > A bleeding problem called Immune Thrombocytopenic Purpura (ITP)
- > Problems of the thyroid gland (hypo/hyper thyroidism)
- > Kidney problems (nephropathies, including anti-glomerular basement membrane [anti-GBM] disease)

**Serious Infections**

**Doctors:** See SmPC for more information.

Phone number	Name	
		Neurologist
		General Practitioner
		MS Nurse

\_\_\_\_\_  
Patient Signature:

\_\_\_\_\_  
Patient Name:

My doctor 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 Alert Card

**Please show this card to all emergency and healthcare providers**

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**<sup>®</sup>  
alemtuzumab<sup>12mg</sup><sub>IV</sub>

## Important side effects to watch for:

**Call your doctor right away to report these symptoms. If you cannot reach your doctor seek immediate medical attention.**

### Autoimmune Conditions

#### 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
- > Heavier, longer or more frequent menstrual periods than normal
- > Bleeding between your menstrual periods could also be a sign of ITP
- > Bleeding from your gums or nose that is new or takes longer than usual to stop
- > Coughing up blood

#### Kidney problems or anti-GBM disease

- > Blood in the urine – it may be red or tea-colored
- > Swelling in your legs or feet
- > Coughing up blood

### Serious Infections

**Also, tell your doctor right away if you have any of these signs of serious infection**

- > Fever and/or chills
- > Swollen glands

Autoimmune conditions 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.

Lemtrada/Patient Card/EU Gen/Release date Nov 2013/EN

#### 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

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](http://www.medicinesauthority.gov.mt/adportal) and posted to Medicines Authority Post-licensing Directorate, 203, Level 3, Rue D'Argens, Gżira GZR 1368, MALTA, or sent by email to [postlicensing.medicinesauthority@gov.mt](mailto:postlicensing.medicinesauthority@gov.mt)

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