

[Treating Provider First Name] [Treating Provider Last Name], [Treating Provider Title]
[Practice Site Name]
[Treating Site HCP Practice Address 1]
[Treating Site HCP Practice City, Site ZIP]

LEMTRADA® (alemtuzumab)

FDA-Required Updated REMS Safety Information

Risk of:

- Autoimmune Conditions
- Infusion Reactions
- Stroke
- Malignancies

[Date]

Dear Healthcare Provider,

The Food and Drug Administration (FDA) has required this safety notice as part of the LEMTRADA REMS (Risk Evaluation and Mitigation Strategy) to highlight new risk information about stroke for LEMTRADA.

The goals of the LEMTRADA REMS have been modified to reflect the following new safety risk added to the BOXED WARNING of the Prescribing Information:

Serious and life-threatening stroke has been reported within 3 days of LEMTRADA administration. Instruct patients to seek immediate medical attention if symptoms of stroke occur.

LEMTRADA REMS Goals

- Informing patients about the serious risks of LEMTRADA, and the need for baseline and periodic monitoring
- Informing healthcare providers about the serious risks of autoimmune conditions, infusion reactions, stroke, and malignancies with LEMTRADA, the need to counsel patients, and the need for baseline and periodic monitoring

LEMTRADA REMS Requirements

- **Prescribers** must be enrolled in the LEMTRADA REMS
- **Healthcare Facilities and Pharmacies** must be enrolled in the LEMTRADA REMS
- **Patients** must be enrolled and authorized in the LEMTRADA REMS

Reporting Adverse Events

Report all suspected adverse events to Genzyme at 1-800-745-4447 (option 2) or the FDA at 1-800-FDA-1088 (1-800-332-1088) or www.fda.gov/medwatch.

This letter does not contain the complete safety profile for LEMTRADA. Please see the enclosed Prescribing Information.

If you have any questions about the LEMTRADA REMS, please call 1-855-676-6326 for more information or visit www.LemtradaREMS.com.

Sincerely,

LEMTRADA REMS

SANOI GENZYME 

LEMTRADA REMS DESKTOP

PUBLIC and Prescriber Desktop Pages Only

PUBLIC FACING PAGES