

What Is the LEMTRADA REMS (Risk Evaluation and Mitigation Strategy)?

A REMS is a strategy to manage known or potential risks associated with a drug. It is required by the FDA to ensure that the benefits of the drug outweigh its risks. Due to serious risks of autoimmune conditions, infusion reactions, stroke and malignancies, LEMTRADA[®] (alemtuzumab) is only available through a restricted program called the LEMTRADA REMS.

LEMTRADA REMS Requirements

- **Prescribers** must be enrolled in the LEMTRADA REMS to be able to prescribe LEMTRADA.
- **Pharmacies** must be enrolled in the LEMTRADA REMS to be able to dispense LEMTRADA.
- **Healthcare Facilities** must be enrolled in the LEMTRADA REMS to be able to dispense and administer LEMTRADA.
- **Patients** must be enrolled and authorized in the LEMTRADA REMS in order to receive LEMTRADA.

PRESCRIBER ENROLLMENT INSTRUCTIONS

1. Complete the training program, which includes reviewing the following:
 - LEMTRADA Prescribing Information
 - LEMTRADA REMS Program Overview
 - *LEMTRADA REMS Education Program for Prescribers*
2. Successfully complete the 8-question LEMTRADA REMS Knowledge Assessment.
3. Enroll in the program by completing a LEMTRADA REMS Prescriber Enrollment Form.
4. Submit the completed and signed Forms to the LEMTRADA REMS.

PHARMACY ENROLLMENT INSTRUCTIONS

1. An authorized representative must enroll on behalf of the pharmacy by reviewing the LEMTRADA REMS Program Overview and completing the LEMTRADA REMS Pharmacy Enrollment Form, which acknowledges that the pharmacy agrees to follow the procedures outlined in the LEMTRADA REMS, including:
 - All relevant staff at the pharmacy who will be involved with the dispensing of LEMTRADA must be educated and trained.
 - The pharmacy will verify that a LEMTRADA REMS Prescription Ordering Form is received for each prescription.
 - The pharmacy will verify that prescribers and healthcare facilities are certified and patients are authorized to receive LEMTRADA prior to dispensing LEMTRADA.
 - Enrollment in the LEMTRADA REMS must be renewed every 2 years from initial enrollment.
2. Submit the completed and signed LEMTRADA REMS Pharmacy Enrollment Form to the LEMTRADA REMS.

HEALTHCARE FACILITY ENROLLMENT INSTRUCTIONS

1. An authorized representative must enroll on behalf of the healthcare facility by reviewing the *LEMTRADA REMS Education Program for Healthcare Facilities* and completing the LEMTRADA REMS Healthcare Facility Enrollment Form, which acknowledges that the healthcare facility agrees to follow the procedures outlined in the LEMTRADA REMS, including:
 - All staff at the facility who will be involved with the dispensing and administration of LEMTRADA must be trained, and a written record of all staff REMS trainings must be kept on file.
 - The healthcare facility will verify that prescribers are certified and patients are authorized to receive LEMTRADA prior to dispensing or administering LEMTRADA.
 - The healthcare facility will provide a copy of *What You Need to Know About LEMTRADA Treatment and Infusion Reactions: A Patient Guide* to the patient on the first day of each treatment course when LEMTRADA is dispensed.
 - The healthcare facility will complete a LEMTRADA REMS Infusion Checklist for each patient at the conclusion of each treatment course and submit it to the LEMTRADA REMS within 5 business days.
 - Enrollment in the LEMTRADA REMS must be renewed every 2 years from initial enrollment.
2. Submit the completed and signed LEMTRADA REMS Healthcare Facility Enrollment Form to the LEMTRADA REMS.

PATIENT ENROLLMENT INSTRUCTIONS

1. Complete the LEMTRADA REMS Patient Enrollment Form, which contains information to be completed by both the prescriber and the patient.
2. Provide a copy of *What You Need to Know About LEMTRADA Treatment: A Patient Guide* and a LEMTRADA Patient Safety Information Card to each patient who will receive LEMTRADA. You must use *What You Need to Know About LEMTRADA Treatment: A Patient Guide* to counsel your patients on the serious risks and REMS requirements with the use of LEMTRADA.
3. Submit the completed and signed LEMTRADA REMS Patient Enrollment Form to the LEMTRADA REMS.
4. Provide the patient with a copy of the LEMTRADA REMS Patient Enrollment Form and keep a copy in the patient's medical record.

Where to Find REMS Information and Resources

To enroll in the LEMTRADA REMS, call 1-855-676-6326. For information related to enrollment in the LEMTRADA REMS, call 1-855-676-6326 or visit www.LemtradaREMS.com

Indication and Usage

LEMTRADA is indicated for the treatment of relapsing forms of multiple sclerosis (MS), to include relapsing-remitting disease and active secondary progressive disease, in adults. Because of its safety profile, the use of LEMTRADA should generally be reserved for patients who have had an inadequate response to two or more drugs indicated for the treatment of MS.

Limitations of Use:

LEMTRADA is not recommended for use in patients with clinically isolated syndrome (CIS) because of its safety profile.

The Prescribing Information includes a **BOXED WARNING** for LEMTRADA.

Please see accompanying Prescribing Information for complete safety information, including **BOXED WARNING**.