A Risk Evaluation and Mitigation Strategy (REMS) is a strategy to manage known or potential serious risks associated with a drug product and is required by the Food and Drug Administration (FDA) to ensure that the benefits of a drug outweigh its risks.

The MYALEPT REMS Program was developed with the FDA:

To educate prescribers about

- the development of anti-metuleptin antibodies that neutralize endogenous leptin and/or MYALEPT and the serious adverse events that may result from these antibodies,
- the risk of lymphoma, and
- appropriate patient selection

**Program Requirements**

MYALEPT is available only through the MYALEPT REMS Program. The MYALEPT REMS Program requirements include:

For Prescribers:

- Certification of prescribers of MYALEPT
  - Certification consists of completion of training, and enrollment in the MYALEPT REMS Program
- Completion of a Prescription Authorization form for each new prescription

Find out more about Training & Enrollment.

For Pharmacies:

- Restricted distribution of MYALEPT to patients with completed Prescription Authorization Forms from prescribers who are certified in the MYALEPT REMS Program

**Training & Enrollment**

Healthcare providers who prescribe MYALEPT must review the prescriber training materials to enroll in the MYALEPT REMS Program.

**Steps to Prescriber Certification**

1. **Review the Prescriber Education Materials**
   - MYALEPT Prescribing Information
   - Prescriber Training Module

2. **Complete and submit the MYALEPT REMS Program Prescriber Enrollment Form**
   - Print and sign the Prescriber Enrollment Form or request a copy by calling 1-855-669-2537
   - Submit the form via fax to 1-877-328-9682

By completing the Prescriber Enrollment Form, the prescriber agrees to comply with the MYALEPT REMS Program requirements. A confirmation of your certification in the MYALEPT REMS Program will be sent to you so you can begin to prescribe MYALEPT.

**Reporting Adverse Reactions**

Healthcare providers should report all suspected adverse events.

Please contact the company at **1-855-669-2537** or FDA at **1-800-FDA-1088** or [www.fda.gov/medwatch.com](http://www.fda.gov/medwatch.com).