MYALEPT® REMS Program

Program Requirements | Training & Enrollment

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 hat the benefits of a drug outweigh its risks.

The MYALEPT REMS Program was developed wi h the FDA:

To educate prescribers about

- he development of an i-metreleptin an ibodies hat neutralize endogenous leptin and/or MYALEPT and the serious adverse events that may result from these antibodies,
- he risk of lymphoma, and
- appropriate pa ient selection

Program Requirements

MYALEPT is available only through he 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 he 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.

REMS Materials

- PDF MYALEPT REMS Program: An Introduction
- PDF MYALEPT REMS Program Prescriber Training Module
- PDF MYALEPT REMS Program Prescriber Enrollment Form
- PDF MYALEPT REMS Program Prescription Authorization Form
- PDF Prescribing Information

MYALEPT REMS Program Contact Us

Phone: 1-855-669-2537
Fax: 1-877-328-9682
Hours of Operation:
Monday - Friday,
8:00am-8:00pm
Eastern Time

Aegerion Pharmaceuticals

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Last Updated 08/2015