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 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-metoleptin 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

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 Prescribing Information

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.

Reference ID: 3811882