

### What is the MYALEPT REMS (Risk Evaluation and Mitigation Strategy) Program?

A REMS is a strategy to manage known or potential risks associated with a drug, and is required by the FDA to ensure that the benefits of the drug outweigh its risks. MYALEPT is available only under a restricted program called the MYALEPT REMS Program because of:

- the development of anti-metreleptin antibodies that neutralize endogenous leptin and/or MYALEPT and the serious adverse events that may result
- the risk of lymphoma

**Because of these risks, appropriate patient selection consistent with the approved indication for MYALEPT is very important.**

### MYALEPT REMS Program Requirements

- Certification of Prescribers of MYALEPT
- Completion of a Prescription Authorization Form for each new prescription
- Restricted distribution of MYALEPT through certified pharmacies

### Certification of Prescribers of MYALEPT

1. Review the Prescribing Information and MYALEPT Prescriber Training Module
  2. Complete, sign, and submit the one-time MYALEPT REMS Program Prescriber Enrollment Form
- All materials can be downloaded from the MYALEPT REMS website at: [www.MYALEPTREMS.com](http://www.MYALEPTREMS.com).  
Or request these materials by calling 1-855-669-2537.

### Completion of Prescription Authorization Form

**Each new prescription for MYALEPT must be written using the MYALEPT Prescription Authorization Form.**

- Download the Prescription Authorization Form at [www.MYALEPTREMS.com](http://www.MYALEPTREMS.com) or request a copy by calling 1-855-669-2537
- Complete the Prescription Authorization Form

### Restricted Distribution of MYALEPT through Certified Pharmacies

Prescription Authorization Form must be signed and submitted by fax to 1-877-328-9682

**Please see accompanying full Prescribing Information including Boxed Warning, or visit [www.MYALEPTREMS.com](http://www.MYALEPTREMS.com)**

**If you have any questions, please contact the MYALEPT REMS Program.**

Phone number: 1-855-669-2537 | Fax number: 1-877-328-9682 | [www.MYALEPTREMS.com](http://www.MYALEPTREMS.com)

**APPENDIX 4**  
**MYALEPT REMS PROGRAM WEBSITE**