

FDA REQUIRED SAFETY INFORMATION
RISK OF SEVERE INFECTIONS
MYALEPT[®] (metreleptin) for Injection

Dear Certified Prescriber:

A recent assessment of the Myalept REMS (Risk Evaluation Mitigation Strategy) Program has demonstrated that prescribers are not fully aware of the 1) serious risk of severe infections associated with the use of MYALEPT and 2) the availability of neutralizing antibody testing.

Therefore, Aegerion has made updates to the MYALEPT REMS Prescriber Training Module to emphasize:

- **the risk of severe infections that may result from the development of anti-metreleptin antibodies, and**
- **the availability of testing for neutralizing activity in patients who experience severe infections, or if you suspect that Myalept is no longer working**

We remind you that the purpose of the MYALEPT REMS Prescriber Training Module is to educate prescribers about:

- The development of anti-metreleptin antibodies that neutralize endogenous leptin and/or Myalept and the serious adverse events that may result from these antibodies, including:
 - severe infections,
 - loss of glycemic control
 - increases in triglycerides
- The risk of lymphoma, and
- Appropriate patient selection

For instructions on how to submit samples for neutralizing antibody testing contact Aegerion Pharmaceuticals, Inc. (Aegerion) at 1-866-216-1526.

Certified Prescribers are encouraged to review the revised prescriber training program that is now located on the MYALEPT REMS website: www.myaleptREMS.com. However, no action is required to maintain your certification.

If you have any questions on the above, please contact the MYALEPT REMS Program at 1-855-669-2537.

Sincerely,



Dr. Charles Gerrits
Aegerion Pharmaceuticals, Inc.

Attachment: Myalept Prescribing Information