

PHARMACY ACTION NEEDED

Subject: Significant Modifications to the JUXTAPID® (lomitapide) capsules Risk Evaluation and Mitigation Strategy (REMS) Program

Pharmacy Action: Recertification Required by 2 July, 2017

Dear Certified Pharmacy:

Aegerion Pharmaceuticals Inc. (Aegerion) has made significant modifications to the REMS for JUXTAPID to help ensure that the benefits of treatment with JUXTAPID outweigh the risk of hepatotoxicity.

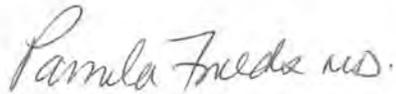
The modifications to the REMS will **require all certified pharmacies to be recertified in the JUXTAPID REMS Program by 2 July, 2017** by doing the following:

1. Designate an Authorized Representative who will be required to:
 - a. **Review** the JUXTAPID:
 - Prescribing Information (PI); and **JUXTAPID REMS Program Fact Sheet** (enclosed)
 - b. **Successfully complete**:
 - The on-line JUXTAPID REMS Program **Pharmacy Training Module** and **Knowledge Assessment**
 - c. **Agree** to:
 - Train all applicable pharmacy staff on the JUXTAPID REMS program requirements.
 - Implement processes and procedures to ensure that the requirements of the JUXTAPID REMS Program are met.
 - Be audited.
 - Provide prescription records to Aegerion.
2. **Submit**:
 - The JUXTAPID REMS Program **Pharmacy Enrollment Form** and the Certificate of Completion for the JUXTAPID REMS Program Pharmacy Training Module and Knowledge Assessment to the JUXTAPID REMS Coordinating Center.

***** Pharmacies who do not recertify in the JUXTAPID REMS Program by 2 July, 2017 will be decertified and will be unable to purchase, dispense or distribute JUXTAPID *****

Complete details about the modified JUXTAPID REMS Program can be found at www.JUXTAPIDREMSProgram.com. For more information, you may also contact the JUXTAPID REMS Program toll-free at 1-855-JUXTAPID (1-855-898-2743).

Sincerely,



Pamela Foulds, M.D.
Chief Medical Officer
Aegerion Pharmaceuticals, Inc.

Attachments:
JUXTAPID REMS Program Fact Sheet
JUXTAPID Prescribing Information