

**Initial REMS Approval: 12/2012**  
**Most Recent Modification: 8/2013**

## **NDA 203858**

### **JUXTAPID (lomitapide) capsules**

**Drug Class:** Microsomal Triglyceride Transfer Protein Inhibitor (MTP-I)

Aegerion Pharmaceuticals, Inc. (Aegerion)  
101 Main Street Suite 1850  
Cambridge, MA 02142  
Telephone: 617-500-7795

## **RISK EVALUATION AND MITIGATION STRATEGY (REMS)**

### **I. GOALS**

The goals of the JUXTAPID REMS Program are:

- To educate prescribers about:
  - the risk of hepatotoxicity associated with the use of JUXTAPID; and
  - the need to monitor patients during treatment with JUXTAPID as per product labeling.
- To restrict access to therapy with JUXTAPID to patients with a clinical or laboratory diagnosis consistent with homozygous familial hypercholesterolemia (HoFH).

### **II. REMS ELEMENTS**

#### **A. Elements to Assure Safe Use**

##### **1. Healthcare Providers (HCP) who prescribe JUXTAPID are specially certified.**

- a. Aegerion will ensure HCPs who prescribe JUXTAPID are specially certified.

To become specially certified to prescribe JUXTAPID, prescribers must enroll in JUXTAPID REMS program. Prescribers must complete the following requirements:

- i. Review the Prescribing Information (PI)
- ii. Complete the *Prescriber Training Module*
- iii. Complete and sign the *Prescriber Enrollment Form* and submit it to the JUXTAPID REMS Program.

- b. Aegerion will:
- i. Ensure that the *Prescriber Training Module* and the *Prescriber Enrollment Form* are available on the JUXTAPID REMS Program website ([www.JUXTAPIDREMSProgram.com](http://www.JUXTAPIDREMSProgram.com)), or can be obtained by contacting the JUXTAPID REMS Program by phone at 1-85-JUXTAPID (1-855-898-2743). Ensure that prescribers complete the *Prescriber Training Module* and *Prescriber Enrollment Form* before activating prescribers' certification in the JUXTAPID REMS Program.
  - ii. Ensure that prescribers are notified when they have been successfully certified by the JUXTAPID REMS Program.
  - iii. Inform certified prescribers following substantial changes to the JUXTAPID REMS or JUXTAPID REMS Program. Substantial changes include: significant changes to the operation of the JUXTAPID REMS Program or changes to the Prescribing Information that affect the risk-benefit profile of JUXTAPID.
  - iv. To facilitate prescriber certification, Aegerion will communicate information to prescribers and professional societies through JUXTAPID REMS Program website and *Dear Healthcare Provider* and *Dear Professional Society* letters.
    - 1) *Dear Healthcare Provider* letter - Aegerion will distribute a *Dear Healthcare Provider* letter within 60 days of JUXTAPID REMS approval to inform potential prescribers about the REMS and the REMS requirements. The *Dear Healthcare Provider* letter will be distributed by mass mailing to healthcare providers certified by the American Board of Clinical Lipidology, directors of apheresis centers, and to healthcare providers known to be experienced in treating patients with HoFH. The letter will be accompanied by the PI and will be available from the JUXTAPID REMS Program website ([www.JUXTAPIDREMSProgram.com](http://www.JUXTAPIDREMSProgram.com)) at the time of the mailing and will remain on the website for 12 months after the mailing, or can be requested from the JUXTAPID REMS Program by phone at 1-85-JUXTAPID (1-855-898-2743).

2) *Dear Professional Society* letter - Aegerion will send a *Dear Professional Society* letter within 60 days of JUXTAPID REMS approval to the leadership of the following professional societies and will request that these societies disseminate the content of the letter to their professional membership:

- a) National Lipid Association
- b) The Endocrine Society
- c) The American Association of Clinical Endocrinologists
- d) American Heart Association
- e) American College of Cardiology
- f) American Society of Preventive Cardiology
- g) Preventive Cardiology Nurses Association
- h) American Society for Apheresis

The letter will be provided to MedWatch at the same time it is provided to the professional organizations.

3) JUXTAPID REMS Program Website - A JUXTAPID REMS Program website ([www.JUXTAPIDREMSProgram.com](http://www.JUXTAPIDREMSProgram.com)) will be available at the time of approval.

The *Prescriber Training Module- downloadable PDF and online versions*, *Prescriber Enrollment Form- downloadable PDF and online versions*, *Dear Healthcare Provider* and *Dear Professional Society* letters, and JUXTAPID REMS Program website are part of the JUXTAPID REMS and are appended.

**2. JUXTAPID will be dispensed only by specially certified pharmacies.**

- a. Aegerion will ensure that JUXTAPID will only be dispensed by certified pharmacies.
- b. To become certified to dispense JUXTAPID, each pharmacy representative must agree to the following:

- i. To educate all pharmacy staff involved in the dispensing of JUXTAPID on the JUXTAPID REMS Program requirements.
- ii. Put processes and procedures in place to verify, prior to dispensing JUXTAPID, that:
  - 1) the prescriber is certified in the JUXTAPID REMS Program.
  - 2) the JUXTAPID REMS *Prescription Authorization Form* is received for each new prescription.
- iii. To be audited to ensure that all processes and procedures are in place and are being followed for the JUXTAPID REMS Program.
- iv. To provide prescription data to the JUXTAPID REMS Program.

The JUXTAPID REMS *Prescription Authorization Form* is part of the REMS and is appended.

**3. JUXTAPID will be dispensed only to patients with evidence or other documentation of safe-use conditions.**

- a. JUXTAPID will only be dispensed to patients whose prescribers are specially certified in the JUXTAPID REMS Program and attest on the JUXTAPID REMS *Prescription Authorization Form* that:
  - i. they understand that JUXTAPID is indicated as an adjunct to a low-fat diet and other lipid-lowering treatments, including LDL apheresis where available, to reduce low-density lipoprotein cholesterol (LDL-C), total cholesterol (TC), apolipoprotein B (apo B), and non-high-density lipoprotein cholesterol (non-HDL-C) in patients with homozygous familial hypercholesterolemia (HoFH);
  - ii. they affirm that their patient has a clinical or laboratory diagnosis consistent with HoFH;
  - iii. they understand that JUXTAPID has not been studied in patients less than 18 years of age; and
  - iv. liver-related laboratory tests have been obtained as directed in the PI.

## **B. Implementation System**

1. Aegerion will ensure that JUXTAPID is distributed to and dispensed only by certified pharmacies.
2. Aegerion will maintain, monitor, and evaluate the implementation of the JUXTAPID REMS program.
  - a. Aegerion will develop and follow written procedures and scripts to implement the REMS.
  - b. Aegerion will maintain a secure, validated database of all certified prescribers and pharmacies that is in compliance with 21 CFR Part 11 regulations.
  - c. Aegerion will send confirmation of certification to each certified pharmacy.
  - d. Aegerion will maintain a JUXTAPID REMS Program Coordinating Center with a Call Center to support patients, prescribers, and pharmacies in interfacing with the JUXTAPID REMS.
  - e. Aegerion will ensure that all materials listed in or appended to the JUXTAPID REMS Program will be available through the JUXTAPID REMS Program website ([www.JUXTAPIDREMSProgram.com](http://www.JUXTAPIDREMSProgram.com)) or by calling the JUXTAPID REMS Program Call Center at 1-85-JUXTAPID (1-855-898-2743).
  - f. If there are substantive changes to the JUXTAPID REMS or JUXTAPID REMS Program, Aegerion will update all affected materials, and notify enrolled prescribers and certified pharmacies, as applicable. Substantive changes are defined as: significant changes to the operation of the JUXTAPID REMS Program or changes to the PI that affect the risk-benefit profile of JUXTAPID.
  - g. Aegerion will monitor and audit the certified pharmacies to ensure that all processes and procedures are in place and functioning to support the requirements of the JUXTAPID REMS Program. Corrective action will be instituted by Aegerion if noncompliance is found.
  - h. Based on monitoring and evaluation of the JUXTAPID REMS elements to assure safe use, Aegerion will take reasonable steps to improve implementation of these elements

and to maintain compliance with the JUXTAPID REMS Program requirements, as applicable.

**C. Timetable for Submission of Assessments**

Aegerion will submit REMS Assessments to the FDA 6 months, 12 months, and annually thereafter from the date of initial approval of this REMS. To facilitate inclusion of as much information as possible while allowing reasonable time to prepare the submission, the reporting interval covered by each assessment should conclude no earlier than 60 days before the submission date for that assessment. Aegerion will submit each assessment so that it will be received by the FDA on or before the due date.