Juxtapid (lomitapide) capsules

REMS Program

What is the JUXTAPID Risk Evaluation and Mitigation Strategy (REMS)?

Due to the risk of hepatotoxicity, JUXTAPID is only available through a restricted distribution program required by the US Food and Drug Administration called the JUXTAPID REMS.

The goal of the JUXTAPID REMS is to mitigate the risk of hepatotoxicity associated with the use of JUXTAPID by ensuring that:

1. Prescribers are educated about the approved indication for JUXTAPID, the risk of hepatotoxicity associated with the use of JUXTAPID, and the need to monitor patients during treatment with JUXTAPID as per product labeling
2. JUXTAPID is dispensed only to patients with a clinical or laboratory diagnosis consistent with HoFH
3. Patients are informed about the risk of hepatotoxicity associated with the use of JUXTAPID and the need for baseline and periodic liver monitoring

JUXTAPID REMS Requirements

- Certification of prescribers of JUXTAPID
- Patient counseling
- Certification of pharmacies to dispense JUXTAPID
- A valid Prescription Authorization Form signed by a certified prescriber
- A completed Patient-Prescriber Acknowledgement Form signed by the patient and a certified prescriber must be on file

Because of the risk of hepatotoxicity with the use of JUXTAPID, prescribers are recommended to monitor liver function as described in the Prescribing Information.

Please see accompanying full Prescribing Information for JUXTAPID, including BOXED WARNING for hepatotoxicity.

Prescriber Requirements

Only certified healthcare providers can prescribe JUXTAPID. To become certified, prescribers must:

1. **Review** the Prescribing Information and this Fact Sheet
2. **Complete** the online Prescriber Training Module and the Prescriber Enrollment Form.
   Submit the Prescriber Enrollment Form and the Certificate of Completion for the Prescriber Training Module to the JUXTAPID REMS Coordinating Center by fax: **1-855-898-2498** or email: **REMS@chiesi.com**
3. **Agree**
   - To counsel each patient on the JUXTAPID REMS including the indication for use, the risk of hepatotoxicity and the need for monitoring using the Patient Guide
   - To complete a Patient-Prescriber Acknowledgement Form with each patient
   - To submit a Prescription Authorization Form for **each** prescription to the JUXTAPID REMS
   - To perform routine liver monitoring for each patient:
     - prior to initiating therapy
     - **monthly** during the first year of treatment
     - every three months thereafter, and before any dose adjustment

Pharmacy Requirements

Only certified pharmacies can purchase, dispense, and distribute JUXTAPID. To become certified, pharmacies must select a representative who will complete the certification process:

1. **Review** the Prescribing Information, and this Fact Sheet
2. **Complete** the online Pharmacy Training Module and the Pharmacy Enrollment Form.
   Submit the Pharmacy Enrollment Form and the Certificate of Completion for the Pharmacy Training Module to the JUXTAPID REMS Coordinating Center by fax: **1-855-898-2498** or email: **REMS@chiesi.com**
3. **Agree** to train all relevant pharmacy staff, to implement processes and procedures to ensure prescriber certification, to be audited if necessary, and to provide prescription data

Visit **www.juxtapidREMSprogram.com** to access training materials and begin certification.

Phone: 1-85-JUXTAPID (1-855-898-2743) | Fax: 1-855-898-2498 | www.juxtapidREMSprogram.com