

Initial REMS approval: 12/2012

Last modified/revised: 10/2020

**NDA 203858 JUXTAPID® (lomitapide)
Microsomal Triglyceride Transfer Protein Inhibitor**

**Amryt Pharmaceuticals DAC
45 Mespil Road
Dublin 4, Ireland
Telephone: +353 1 518 0200**

RISK EVALUATION AND MITIGATION STRATEGY (REMS)

I. GOAL

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

- 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.
- JUXTAPID is dispensed only to patients with a clinical or laboratory diagnosis consistent with homozygous familial hypercholesterolemia (HoFH).
- Patients are informed about the risk of hepatotoxicity associated with the use of JUXTAPID and the need for baseline and periodic monitoring.

II. REMS ELEMENTS

A. Elements to Assure Safe Use

1. Healthcare Providers (HCP) who prescribe JUXTAPID must be certified.

- a. To become certified to prescribe JUXTAPID, healthcare providers must:
 - i. Review the Prescribing Information for JUXTAPID.
 - ii. Review the *JUXTAPID REMS Program Fact Sheet*.
 - iii. Complete the *JUXTAPID REMS Program Prescriber Training Module* and successfully complete the *Knowledge Assessment*.
 - iv. Enroll in the JUXTAPID REMS Program by completing the *JUXTAPID REMS Program Prescriber Enrollment Form* and submitting it to the JUXTAPID REMS Program.

- b. As a condition of certification, prescribers must:
- i. Review the *JUXTAPID REMS Program Patient Guide* with each patient and counsel the patient about the appropriate use and risks associated with JUXTAPID and provide the patient a copy.
 - ii. Complete the *JUXTAPID REMS Program Patient-Prescriber Acknowledgement Form* for each patient and submit to the JUXTAPID REMS Program Coordinating Center.
 - iii. Perform the following on an ongoing basis for each patient: Complete and submit a *JUXTAPID REMS Program Prescription Authorization Form* for each new JUXTAPID prescription.
- c. Amryt must:
- i. Ensure that healthcare providers who prescribe JUXTAPID are certified, in accordance with the requirements described above.
 - ii. Provide all of the following mechanisms for healthcare providers to complete the certification process for the JUXTAPID REMS Program: email and fax.
 - iii. Ensure that healthcare providers are notified when they have been certified by the JUXTAPID REMS Program.
 - iv. Maintain a validated, secure database of healthcare providers who are certified to prescribe JUXTAPID in the JUXTAPID REMS Program.
 - v. Ensure that healthcare providers meet the REMS requirements and de-certify healthcare providers who do not maintain compliance with REMS requirements.
 - vi. Provide the *JUXTAPID REMS Program Fact Sheet*, *JUXTAPID REMS Program Prescriber Training Module*, *JUXTAPID REMS Program Patient Guide*, *JUXTAPID REMS Program Patient-Prescriber Acknowledgement Form*, *JUXTAPID REMS Program Prescription Authorization Form* and the JUXTAPID Prescribing Information to healthcare providers who (1) attempt to prescribe JUXTAPID and are not yet certified, or (2) inquire about how to become certified.
 - vii. Send a *REMS Letter for Healthcare Providers* within 60 calendar days of the approval of the REMS modification (01/03/2017) to certified prescribers. The letter must be accompanied by the *JUXTAPID REMS Program Fact Sheet* and the Prescribing Information. The *REMS Letter* must also be available from the JUXTAPID REMS Program Website (www.juxtapidREMSprogram.com) at the time of the mailing, remain on the website for 6 months after the mailing and can be requested from the JUXTAPID REMS Program by phone at 1-85-JUXTAPID (1-855-898-2743).

The following materials are part of the REMS and are appended:

- *JUXTAPID REMS Program Prescriber Enrollment Form*
- *JUXTAPID REMS Program Prescriber Training Module and Knowledge Assessment*
- *JUXTAPID REMS Program Fact Sheet*
- *JUXTAPID REMS Program Patient Guide*
- *JUXTAPID REMS Program Patient-Prescriber Acknowledgement Form*
- *JUXTAPID REMS Program Prescription Authorization Form*
- *JUXTAPID REMS Letter for Healthcare Providers*
- *JUXTAPID REMS Program Website (www.juxtapidREMSprogram.com)*

2. Pharmacies that dispense JUXTAPID must be certified.

- a. To become certified to dispense JUXTAPID, pharmacies must:
 - i. Designate an authorized representative to complete the certification process by submitting the completed *JUXTAPID REMS Program Pharmacy Enrollment Form* on behalf of the pharmacy.
 - ii. Ensure that the authorized representative oversees implementation and compliance with the JUXTAPID REMS Program requirements by the following:
 - 1) Review the Prescribing Information.
 - 2) Review the *JUXTAPID REMS Program Fact Sheet*.
 - 3) Complete the *JUXTAPID REMS Program Pharmacy Training Module* and successfully complete the *Knowledge Assessment*.
 - 4) Ensure all relevant staff involved in the dispensing of JUXTAPID are trained on the JUXTAPID REMS Program requirements as described in the *JUXTAPID REMS Program Pharmacy Training Module* and maintain a record of training.
 - 5) Put processes and procedures in place to ensure the following requirements are completed prior to dispensing JUXTAPID:
 - a) Verify the *JUXTAPID REMS Program Patient-Prescriber Acknowledgement Form* is completed by accessing the JUXTAPID REMS Program database or by calling the JUXTAPID REMS Program Coordinating Center for verification.
 - b) Verify the prescriber is certified in the JUXTAPID REMS Program by accessing the JUXTAPID REMS Program database or by calling the JUXTAPID REMS Program Coordinating Center for verification.
 - c) Verify a *JUXTAPID REMS Program Prescription Authorization Form* is received for each new JUXTAPID prescription.

- b. As a condition of certification:
- i. The certified pharmacy must recertify in the JUXTAPID REMS Program if a pharmacy designates a new authorized representative.
 - ii. Maintain documentation that all processes and procedures are in place and are being followed for the JUXTAPID REMS Program and provide upon request to Amryt, FDA, or a third party acting on behalf of Amryt or FDA.
 - iii. Comply with audits by Amryt, FDA, or a third party acting on behalf of Amryt or FDA to ensure that all processes and procedures are in place and are being followed for the JUXTAPID REMS Program.
 - iv. Provide prescription data to Amryt.
- c. Amryt must:
- i. Ensure that pharmacies that dispense JUXTAPID are certified, in accordance with the requirements described above.
 - ii. Provide all the following mechanisms for pharmacies to complete certification for the JUXTAPID REMS Program: email and fax.
 - iii. Ensure that pharmacies are notified when they have been certified by the JUXTAPID REMS Program.
 - iv. Ensure that certified pharmacies are provided access to a database of certified prescribers, and patients who have a completed *JUXTAPID REMS Program Patient-Prescriber Acknowledgement Form*.
 - v. Verify every 12 months that the authorized representative's name and contact information corresponds to that of the current designated authorized representative for the certified pharmacy. If different, the pharmacy must be required to re-certify with a new authorized representative.
 - vi. Send a *REMS Letter for Pharmacists* within 60 calendar days of the approval of the REMS modification (01/03/2017). The letter must be accompanied by the *JUXTAPID REMS Program Fact Sheet* and the Prescribing Information.

The following materials are part of the REMS and are appended:

- *JUXTAPID REMS Program Pharmacy Training Module* and *Knowledge Assessment*
- *JUXTAPID REMS Program Pharmacy Enrollment Form*
- *JUXTAPID REMS Letter for Pharmacists*

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

- a. Patients/caregivers must sign a *JUXTAPID REMS Program Patient-Prescriber Acknowledgement Form* indicating that he/she has:
 - i. Received and has read the *JUXTAPID REMS Program Patient Guide*
 - ii. Received counselling from the prescriber regarding:
 - 1) the risk of hepatotoxicity
 - 2) periodic liver function monitoring
 - 3) appropriate patient selection
- b. To authorize a patient to receive JUXTAPID under the JUXTAPID REMS Program, a certified prescriber must complete a *JUXTAPID REMS Program Prescription Authorization Form* for each new JUXTAPID prescription.
- c. Amryt must:
 - i. Provide all of the following mechanisms for the certified prescriber to be able to submit the completed *JUXTAPID REMS Program Patient-Prescriber Acknowledgement Form* to the JUXTAPID REMS Program: fax.
 - ii. Ensure that the certified pharmacies complete the verifications required under [Section A.2](#) for patients prior to dispensing.
 - iii. Ensure that the certified pharmacies are able to verify JUXTAPID is dispensed to patients only if there is evidence or other documentation that they have met the following requirements:
 - 1) Patient's *JUXTAPID REMS Program Patient-Prescriber Acknowledgement Form* is completed
 - 2) Prescriber is certified
 - 3) *JUXTAPID REMS Program Prescription Authorization Form* is received for each new JUXTAPID prescription

B. Implementation System

1. Amryt must ensure that JUXTAPID is only distributed to certified pharmacies by:
 - a. Ensuring that wholesalers/distributors who distribute JUXTAPID comply with the program requirements for wholesalers/distributors. The wholesaler/distributor must:
 - i. Put processes and procedures in place to verify, prior to distributing JUXTAPID that the pharmacies are certified.

- ii. Train all relevant staff on the JUXTAPID REMS Program requirements.
 - iii. Comply with audits by Amryt, FDA, or a third party acting on behalf of Amryt or FDA to ensure that all processes and procedures are in place and are being followed for the JUXTAPID REMS Program. In addition, wholesalers/distributors must maintain documentation to support that all processes and procedures are in place, are being followed, and make the documentation available for audits.
 - iv. Provide distribution data to Amryt to verify compliance with the JUXTAPID REMS Program.
 - b. Ensuring that wholesaler/distributors maintain distribution records of all shipments of JUXTAPID and provide the data to the JUXTAPID REMS Program.
2. Amryt must monitor distribution data to ensure all the processes and procedures are in place and functioning to support the requirements of the JUXTAPID REMS Program.
 3. Amryt must audit the wholesalers/distributors within 60 calendar days after the wholesaler/distributor is authorized to ensure that all processes and procedures are in place and functioning to support the requirements of the JUXTAPID REMS Program. Corrective action must be instituted by Amryt if noncompliance is identified.
 4. Amryt must maintain a validated, secure database of certified pharmacies and prescribers in the JUXTAPID REMS Program.
 5. Amryt must maintain a validated, secure database of patients who have a completed *JUXTAPID REMS Program Patient-Prescriber Acknowledgement Form*.
 6. Amryt must maintain records of JUXTAPID distribution and dispensing, certified prescribers, certified pharmacies, wholesalers/distributors, and patients who have a completed *Juxtapid REMS Program Patient-Prescriber Acknowledgement Form* to meet REMS requirements.
 7. Amryt must maintain a JUXTAPID REMS Program Call Center 1-85-JUXTAPID (1-855-898-2743) and the JUXTAPID REMS Program Website (www.juxtapidREMSprogram.com). The REMS Program Website must include the capability to complete the prescriber and pharmacy *Knowledge Assessments* online, the option to print the PI, Medication Guide, and JUXTAPID REMS materials. The JUXTAPID product website must include a prominent REMS-specific link to JUXTAPID REMS Program Website. The JUXTAPID REMS Program Website must not link back to the product website(s).
 8. Amryt must ensure the JUXTAPID REMS Program Website is fully operational and the REMS materials listed in or appended to the JUXTAPID REMS document are available through the JUXTAPID REMS Program Website and by calling the JUXTAPID REMS Program Call Center.
 9. Amryt must monitor on an ongoing basis the certified pharmacies to ensure the requirements of the JUXTAPID REMS Program are being met. Amryt must institute corrective action if noncompliance is identified and decertify pharmacies that do not maintain compliance with the JUXTAPID REMS Program requirements.
 10. Amryt must maintain an ongoing annual audit plan and conduct annual audits that involves wholesalers, distributors, and pharmacies.

11. Amryt must audit all certified pharmacies within 60 calendar days after the pharmacy is certified to ensure that all processes and procedures are in place and functioning to support the requirements of the JUXTAPID REMS Program. The certified pharmacies must also be included in Amryt's ongoing annual audit plan. Amryt must institute corrective action if noncompliance is identified.
12. Amryt must take reasonable steps to improve implementation of and compliance with the requirements in the JUXTAPID REMS Program based on monitoring and evaluation of the JUXTAPID REMS Program.

III. Timetable for Submission of Assessments

Amryt must submit REMS assessments to the FDA at 6 months, 12 months, and annually from the date of the initial approval of the REMS (12/21/2012). 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 calendar days before the submission date for that assessment. Amryt must submit each assessment so that it will be received by the FDA on or before the due date.

Appendix 1: REMS Materials

- **PRESCRIBER ENROLLMENT FORM**
- **PRESCRIBER TRAINING MODULE AND KNOWLEDGE ASSESSMENT**
- **FACT SHEET**
- **PATIENT GUIDE**
- **PATIENT-PRESCRIBER ACKNOWLEDGMENT FORM**
- **PRESCRIPTION AUTHORIZATION FORM**
- **LETTER FOR HEALTHCARE PROVIDERS**
- **WEBSITE**
- **PHARMACY TRAINING MODULE AND KNOWLEDGE ASSESSMENT**
- **PHARMACY ENROLLMENT FORM**
- **LETTER FOR PHARMACISTS**

THERE ARE **2** PAGES TO THIS FORM • ALL FIELDS ARE REQUIRED • PLEASE PRINT

JUXTAPID is only available through the JUXTAPID Risk Evaluation and Mitigation Strategy (REMS) Program.

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*All prescribers of JUXTAPID must become certified in the JUXTAPID REMS Program.
The 3-step process for prescriber certification is outlined below.*

- 1. **REVIEW** the JUXTAPID Prescribing Information and JUXTAPID REMS Program Fact Sheet
- 2. **COMPLETE** the online JUXTAPID REMS Program Prescriber Training Module and JUXTAPID REMS Program Prescriber Enrollment Form
- 3. **AGREE** to counsel each patient using the Patient Guide, and to complete a JUXTAPID REMS Program Patient-Prescriber Acknowledgement Form with each patient

PRESCRIBER INFORMATION

First Name: _____ Middle Initial: _____ Last Name: _____

Credentials: MD DO NP PA Other (specify): _____

Physician Specialty: Cardiology Endocrinology Internal Medicine Other (specify): _____

Practice Type (check all that apply): Individual Practice Group Practice Hospital University (Academic) Center

Practice/Facility Name: _____ Department: _____

Address: _____

City: _____ State: _____ Zip: _____

Phone: _____ Fax: _____

Email: _____ NPI #: _____

OFFICE CONTACT

First Name: _____ Last Name: _____

Phone (if different from above): _____ Fax (if different from above): _____

Email: _____

If you have any questions, please contact the JUXTAPID REMS Coordinating Center.
Phone: 1-85-JUXTAPID (1-855-898-2743) | Fax: 1-855-898-2498 | www.juxtapidREMSprogram.com

PRESCRIBER ATTESTATION

By signing this form, I attest that:

- I understand that JUXTAPID® (lomitapide) capsules is only available through the JUXTAPID REMS Program and that I must comply with the program requirements in order to prescribe JUXTAPID.

Use:

- I understand that JUXTAPID is only 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).
- I understand that the safety and effectiveness of JUXTAPID has not been established in patients with hypercholesterolemia who do not have HoFH, including those with heterozygous familial hypercholesterolemia (HeFH).

Hepatotoxicity Risk:

- I understand that there is a risk of hepatotoxicity associated with JUXTAPID.
- I understand the Recommendations for Monitoring of Transaminases with JUXTAPID treatment:
 - Measure serum ALT, AST, alkaline phosphatase and total bilirubin before initiating therapy with JUXTAPID.
 - During the first year of treatment, liver-related laboratory tests (ALT and AST at a minimum) must be measured prior to each increase in dose or monthly, whichever comes first.
 - After the first year, these parameters should be measured at least every 3 months and before any increase in dose.

REMS Program Requirements:

- I have reviewed the JUXTAPID Prescribing Information and the JUXTAPID REMS Program Fact Sheet.
- I have completed the JUXTAPID REMS Program Prescriber Training Module including the Knowledge Assessment for Healthcare Providers.
- I agree to counsel patients on the approved indication for use in patients with HoFH, the risk of hepatotoxicity with JUXTAPID and the need for regular monitoring using the JUXTAPID REMS Patient Guide.
- I agree to complete and sign the Patient-Prescriber Acknowledgement Form with the patient.
- I agree to complete and sign the JUXTAPID REMS Prescription Authorization Form for each prescription.
- I agree that personnel from the JUXTAPID REMS Program may contact me to gather further information or resolve discrepancies or to provide other information related to JUXTAPID or the JUXTAPID REMS Program.
- I agree that Amryt, its agents and contractors such as the pharmacy providers may contact me via phone, mail, or email to survey me on the effectiveness of the program requirements for the JUXTAPID REMS Program.

Prescriber Signature: _____ Date: _____

Prescriber Name: _____ Phone: _____

IMPORTANT

REVIEW TO ENSURE ALL FIELDS ARE COMPLETED • RETURN BOTH PAGES

Fax it to 1-855-898-2498. Or scan and email it to REMS@amrytpharma.com

If you have any questions, please contact the JUXTAPID REMS Coordinating Center.

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

Note to Reviewer:

The Juxtapid Prescriber Training and Knowledge Assessment can be accessed online by clicking the link on the website. The participant will need to register to enter the training and knowledge assessment module.

Participants will be required to enter their name, practice name, city, state and zip code and NPI number. The participant's email address will be requested, if this is not provided the participant will be able to continue.

JUXTAPID[®] (lomitapide)

Risk Evaluation and Mitigation Strategy (REMS) Program

PRESCRIBER TRAINING MODULE and KNOWLEDGE ASSESSMENT

This interactive tool:

- Provides an overview of the JUXTAPID REMS Program
- Discusses the risk of hepatotoxicity with JUXTAPID and the recommended hepatic monitoring requirements and dose adjustments, and
- Provides an overview of the prescriber, patient and pharmacy requirements for the JUXTAPID REMS program

User Guide

To become certified to prescribe JUXTAPID all prescribers must:

- **Successfully** complete this **Prescriber Training Module & Knowledge Assessment**
- **Submit** the signed **Juxtapid REMS Program Prescriber Enrollment Form** to the JUXTAPID REMS Coordinating Center
either by fax: 1-855-898-2498 or email: REMS@amrytpharma.com

At the end of the training module there is a Knowledge Assessment with interactive questions that you must pass. If your answer is incorrect you will be directed back to the relevant page in the materials and will be required to re-answer the question.

This prescriber training module and knowledge assessment is intended to be read in conjunction with the JUXTAPID REMS Factsheet and the JUXTAPID Prescribing Information (PI).

This program is expected to take **15-20** minutes.

Click here to begin



REMS PROGRAM

Prescriber Training Module and Knowledge Assessment

Contents

- Overview of the JUXTAPID REMS Program
- Key JUXTAPID Product Information
- JUXTAPID REMS Program Information
- Knowledge Assessment



Contents

- Overview of the JUXTAPID REMS Program**
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Overview

As there is a risk of hepatotoxicity with the use of JUXTAPID it is only available through a restricted program called the “JUXTAPID Risk Evaluation and Mitigation Strategy (REMS) Program”

The purpose of this training module is to educate health care professionals about the JUXTAPID REMS Program.



A Risk Evaluation and Mitigation Strategy is a strategy to manage known or potential serious risks associated with a drug product and is required by the Food and Drug Administration (FDA) for some products to ensure that the benefits of the drug outweigh its risks.



JUXTAPID REMS Program Goals

The aim of the JUXTAPID REMS Program 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 the product labeling.

② JUXTAPID is dispensed only to patients with a clinical or laboratory diagnosis consistent with homozygous familial hypercholesterolemia (HoFH)

and

③ Patients are informed about the risk of hepatotoxicity associated with the use of JUXTAPID and the need for baseline and periodic monitoring



Contents

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Indication

JUXTAPID is only 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).

Limitations of Use Related to the REMS:

- The safety and effectiveness of JUXTAPID have not been established in patients with hypercholesterolemia who do not have HoFH, including those with heterozygous familial hypercholesterolemia (HeFH).

✦
Please see JUXTAPID full Prescribing Information for the limitations to use, and the **BOXED WARNING** on hepatotoxicity as included on www.juxtapidREMSprogram.com



Appropriate Patient Selection

JUXTAPID is indicated only for use in patients with HoFH.

- Patients must have a clinical or laboratory diagnosis consistent with HoFH.

Contraindications Related to the REMS:

- **Moderate or severe hepatic impairment or active liver disease** including unexplained persistent abnormal liver function tests.



Please see JUXTAPID full Prescribing Information as included on www.juxtapidREMSprogram.com for the full contraindications



Boxed Warning – Hepatic Information

JUXTAPID can cause elevations in transaminases. In the JUXTAPID clinical trial, 10 (34%) of the 29 patients treated with Juxtapid had at least one elevation in alanine aminotransferase (ALT) or aspartate aminotransferase (AST) $\geq 3x$ upper limit of normal (ULN). There were no concomitant clinically meaningful elevations of total bilirubin, international normalized ratio (INR), or alkaline phosphatase.

JUXTAPID also increases hepatic fat, with or without concomitant increases in transaminases. The median absolute increase in hepatic fat was 6% after both 26 and 78 weeks of treatment, from 1% baseline, measured by magnetic resonance spectroscopy. Hepatic steatosis associated with JUXTAPID treatment may be a risk factor for progressive liver disease, including steatohepatitis and cirrhosis.

Measure ALT, AST, alkaline phosphatase, and total bilirubin before initiating treatment and then ALT and AST regularly as recommended. During treatment adjust dose of Juxtapid if the ALT or AST are $\geq 3x$ ULN. Discontinue JUXTAPID for clinical significant liver toxicity.



Please see JUXTAPID full Prescribing Information including the full **BOXED WARNING** as included on www.juxtapidREMSprogram.com



REMS PROGRAM

Prescriber Training Module a

Risk of Hepatotoxicity: JUXTAPID can Cause Elevations in Transaminases

Elevations in transaminases (alanine aminotransferase [ALT] and/or aspartate aminotransferase [AST]) are associated with JUXTAPID. In the clinical trial, 10 (34%) of the 29 patients with HoFH had at least one elevation in ALT or AST $\geq 3x$ ULN, and 4 (14%) of the patients had at least one elevation in ALT or AST $\geq 5x$ ULN. There were no concomitant or subsequent clinically meaningful elevations in bilirubin, INR, or alkaline phosphatase.

Although cases of hepatic failure have not been reported, there is concern that JUXTAPID could induce steatohepatitis, which can progress to cirrhosis over several years.

If transaminase elevations are accompanied by clinical symptoms of liver injury, such as nausea, vomiting, abdominal pain, fever, jaundice, lethargy, flu-like symptoms, increases in bilirubin $\geq 2x$ ULN, or active liver disease, discontinue treatment with JUXTAPID and identify the probable cause.

Continued next slide



REMS PROGRAM

Prescriber Training Module and Knowledge Assessment

Risk of Hepatotoxicity

JUXTAPID Increases Hepatic Fat

Continued from previous slide

JUXTAPID increases hepatic fat, with or without concomitant increases in transaminases.

The median absolute increase in hepatic fat was 6% after both 26 and 78 weeks of treatment, from 1% baseline, measured by magnetic resonance spectroscopy. Hepatic steatosis associated with JUXTAPID treatment may be a risk factor for progressive liver disease, including steatohepatitis and cirrhosis.

Clinical data suggest that hepatic fat accumulation is reversible after stopping treatment with JUXTAPID, but whether histological sequelae remain is unknown.

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REMS PROGRAM

Prescriber Training Module and Knowledge Assessment

Dosage & Administration

The recommended starting dose of JUXTAPID is 5 mg taken once daily (QD).

The dose should be escalated gradually based on acceptable safety and tolerability.

- After two weeks, increase the dose based on acceptable safety and tolerability to 10 mg, taken once daily.
- Then, at a minimum of four week intervals, increase dose to 20 mg, 40 mg, or 60 mg daily.

QD Dose	Duration of Administration Before Considering Dose Increase
5 mg	At least two weeks
10 mg	At least four weeks
20 mg	
40 mg	
60 mg	Maximum recommended dose



Monitoring of transaminases

Timing

Liver monitoring recommendations

Prior to initiating JUXTAPID

Alanine aminotransferase (ALT), aspartate aminotransferase (AST), alkaline phosphatase, and total bilirubin

If abnormal, consider initiating JUXTAPID only after an appropriate workup and the baseline abnormalities have been explained or resolved.

During the first year of treatment

ALT and AST (at a minimum) prior to each increase in dose or monthly, whichever occurs first

After the first year of treatment

ALT and AST (at a minimum) at least every 3 months and before any increase in dose

At any time during treatment

If transaminases are abnormal, reduce or withhold dosing of JUXTAPID and monitor as recommended in the Prescribing Information. Discontinue JUXTAPID for persistent or clinically significant elevations.

If transaminase elevations are accompanied by clinical symptoms of liver injury (such as nausea, vomiting, abdominal pain, fever, jaundice, lethargy, flu-like symptoms), increases in bilirubin $\geq 2x$ ULN, or active liver disease, discontinue treatment with JUXTAPID and identify the probable cause.



Hepatic Monitoring Recommendations

Continued from previous slide

ALT or AST	Treatment and Monitoring Recommendations*
≥3x and <5x ULN	<ul style="list-style-type: none">• Confirm elevation with a repeat measurement within one week.• If confirmed, reduce the dose and obtain additional liver-related tests if not already measured (such as alkaline phosphatase, total bilirubin, and INR).• Repeat tests weekly and withhold dosing if there are signs of abnormal liver function (increase in bilirubin or INR), if transaminase levels rise above 5x ULN, or if transaminase levels do not fall below 3x ULN within approximately 4 weeks. In these cases of persistent or worsening abnormalities, also investigate to identify the probable cause.• If resuming JUXTAPID after transaminases resolve to <3x ULN, consider reducing the dose and monitor liver-related tests more frequently.
≥5x ULN	<ul style="list-style-type: none">• Withhold dosing, obtain additional liver-related tests if not already measured (such as alkaline phosphatase, total bilirubin, and INR), and investigate to identify the probable cause.• If resuming JUXTAPID after transaminases resolve to <3x ULN, reduce the dose and monitor liver-related tests more frequently.

If transaminase elevations are accompanied by clinical symptoms of liver injury (such as nausea, vomiting, abdominal pain, fever, jaundice, lethargy, flu-like symptoms), increases in bilirubin $\geq 2x$ ULN, or active liver disease, discontinue treatment with JUXTAPID and investigate to identify the probable cause



*Recommendations based on an ULN of approximately 30-40 international units/L

REMS PROGRAM

Prescriber Training Module and Knowledge Assessment

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- Knowledge Assessment



JUXTAPID REMS Program Goals

The aim of the JUXTAPID REMS Program 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 the product labeling.

② JUXTAPID is dispensed only to patients with a clinical or laboratory diagnosis consistent with homozygous familial hypercholesterolemia (HoFH)

and

③ Patients are informed about the risk of hepatotoxicity associated with the use of JUXTAPID and the need for baseline and periodic monitoring.



JUXTAPID REMS Key Elements

Prescriber

Prescribers
must be certified
to prescribe
JUXTAPID

Patient

Patients must undergo education about the approved indication for use (HoFH) and the risk of hepatotoxicity with JUXTAPID and the need for regular monitoring as part of the REMS Program.

Pharmacy

Pharmacies
must be certified
to distribute and
dispense
JUXTAPID



REMS PROGRAM

Prescriber Training Module and Knowledge Assessment

Prescriber Certification Process

① REVIEW the JUXTAPID

- JUXTAPID Prescribing Information
- JUXTAPID REMS Program **Fact Sheet**

② COMPLETE the JUXTAPID REMS Program

- **Prescriber Training Module** and Knowledge Assessment

③ AGREE to:

- Counsel patients using the JUXTAPID REMS Program **Patient Guide**
- Complete, sign and submit the JUXTAPID REMS Program **Patient-Prescriber Acknowledgement Form** with the patient
- Submit a JUXTAPID REMS Program **Prescription Authorization Form** for each prescription

④ SUBMIT to the REMS Coordinating Center the:

- Completed JUXTAPID REMS Program **Prescriber Enrollment Form**



JUXTAPID Prescription Process

1

- **Certify** as a Prescriber in the JUXTAPID REMS Program*

2

- **Review** Patient Guide with Patient
- Complete & Sign Patient Prescriber Acknowledgement Form (PPAF), give copy of Patient Guide PPAF to Patient
- Submit the PPAF to JUXTAPID REMS Program

3

- **Complete & Sign the Prescription Authorization Form (PAF)**
- Fax the PAF to the JUXTAPID REMS Program



*prescribers are only required to certify one time

JUXTAPID REMS Program:

Email: REMS@amrytpharma.com

☎ 1-855-898-2743 fax: 1-855-898-2498

REMS PROGRAM

Prescriber Training Module and Knowledge Assessment

Where do I find the REMS Program Materials?

All JUXTAPID REMS Program materials can be found on the JUXTAPID REMS Program website:

www.juxtapidREMSprogram.com

REMS Materials can also be requested by contacting the JUXTAPID REMS Coordinating Center at:

 1- 855-898-2743



Knowledge Assessment



REMS PROGRAM

Prescriber Training Module and Knowledge Assessment

Question 1

The goals of the JUXTAPID REMS program are:

(check the answer that is the most inclusive)

- To educate prescribers about the risk of hepatotoxicity with the use of JUXTAPID.
- To restrict the use of JUXTAPID to only those patients with a clinical and laboratory diagnosis of HoFH.
- To ensure both prescribers and patients understand the risk of hepatotoxicity with JUXTAPID and the need for monitoring of liver function.
- All of the above.



Question 1

The goals of the JUXTAPID REMS program are:

(check the answer that is the most inclusive)

- To educate prescribers about the risk of hepatotoxicity with the use of JUXTAPID.
- To restrict the use of JUXTAPID to only those patients with a diagnosis of HoFH.
- To ensure both prescribers and patients understand the risks of JUXTAPID and the need for monitoring of liver function.
- All of the above.



Partly correct

The education of prescribers about the risk of hepatotoxicity with the use of JUXTAPID is a key part of the JUXTAPID REMS Program. However there are other goals. Review the [REMS Program goals](#) and try again

Question 1

The goals of the JUXTAPID REMS program are:

(check the answer that is the most inclusive)

- To educate prescribers about the risk of hepatotoxicity with the use of JUXTAPID.
- To restrict the use of JUXTAPID to only those patients with a clinical or laboratory diagnosis of HoFH.**
- To ensure both prescribers and patients understand the risks of JUXTAPID and the need for monitoring of liver function.
- All of the above.

 **Partly correct**

The restriction of the use of JUXTAPID to patients with a clinical or laboratory diagnosis of HoFH is a key part of the JUXTAPID REMS Program. However there are other goals. Review the [REMS Program goals](#) and try again



Question 1

The goals of the JUXTAPID REMS program are:

(check the answer that is the most inclusive)

- To educate prescribers about the risk of hepatotoxicity with the use of JUXTAPID.
- To restrict the use of JUXTAPID to only those patients with a diagnosis of HoFH.
- To ensure both prescribers and patients understand JUXTAPID and the need for monitoring of liver function tests.**
- All of the above.

 **Partly correct**

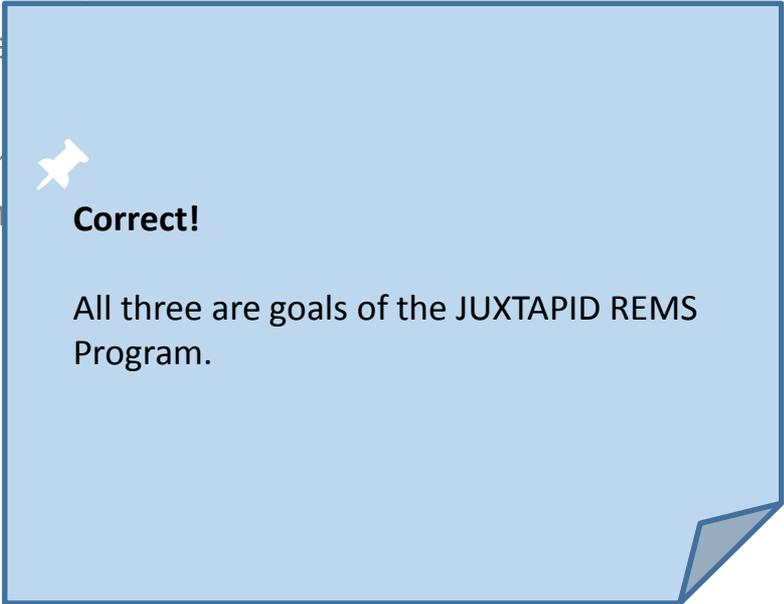
The education of both prescribers and patients about the risk of hepatotoxicity with JUXTAPID and the need for monitoring is an important part of the JUXTAPID REMS Program. However, there are other goals. Review the [REMS Program goals](#) and try again

Question 1

The goals of the JUXTAPID REMS program are:

(check the answer that is the most inclusive)

- To educate prescribers about the risk of hepatotoxicity with the use of JUXTAPID.
- To restrict the use of JUXTAPID to only those patients with a diagnosis of HoFH.
- To ensure both prescribers and patients understand the risks of JUXTAPID and the need for monitoring of liver function.
- All of the above.**



Correct!

All three are goals of the JUXTAPID REMS Program.



Click here to advance



Question 2

Which conditions are appropriate for the use of JUXTAPID?

- a. Mixed dyslipidemia.
- b. Homozygous familial hypercholesterolemia (HoFH).
- c. Heterozygous familial hypercholesterolemia (HeFH).
- d. All of the above.



Question 2

Which conditions are appropriate for the use of JUXTAPID?

- a. Mixed dyslipidemia.**
- b. Homozygous familial hypercholesterolemia (HoFH).
- c. Heterozygous familial hypercholesterolemia (HeFH).
- d. All of the above.



Incorrect

JUXTAPID is indicated for use in patients with homozygous familial hypercholesterolemia (HoFH).

Review the [Indication](#) for JUXTAPID and try again

Question 2

Which conditions are appropriate for the use of JUXTAPID?

- a. Mixed dyslipidemia.
- b. Homozygous familial hypercholesterolemia (HoFH).**
- c. Heterozygous familial hypercholesterolemia (HeFH).
- d. All of the above.

 **Correct!**

JUXTAPID is indicated for use 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).



[Click here to advance](#)



Question 2

Which conditions are appropriate for the use of JUXTAPID?

- a. Mixed dyslipidemia.
- b. Homozygous familial hypercholesterolemia (HoFH).
- c. Heterozygous familial hypercholesterolemia (HeFH).**
- d. All of the above.



Incorrect

JUXTAPID is indicated for use in patients with homozygous familial hypercholesterolemia (HoFH).

Review the [Indication](#) for JUXTAPID and try again

Question 2

Which conditions are appropriate for the use of JUXTAPID?

- a. Mixed dyslipidemia.
- b. Homozygous familial hypercholesterolemia (HoFH).
- c. Heterozygous familial hypercholesterolemia (HeFH).
- d. All of the above.**



Incorrect

JUXTAPID is indicated for use in patients with homozygous familial hypercholesterolemia (HoFH).

Review the [Indication](#) for JUXTAPID and try again

Question 3

What are the hepatic monitoring recommendations during the first year of treatment with Juxtapid?

- a. Check transaminases only if the patient experiences signs and symptoms of liver injury.
- b. Monitor transaminase levels every 3 months.
- c. Monitor ALT and AST (at a minimum) prior to each increase of dose or monthly, what ever occurs first.



Question 3

What are the hepatic monitoring recommendations during the first year of treatment with JUXTAPID?

- a. Check transaminases only if the patient experiences signs and symptoms of liver injury.
- b. Monitor transaminase levels every 3 months
- c. Monitor ALT and AST (at a minimum) prior to what ever occurs first.



Incorrect

During the first year of therapy transaminases should be monitored every 30 days or prior to each increase in dose.

At a minimum ALT and AST should be checked every 30 days.

Review the [Hepatic Monitoring Recommendations](#) for JUXTAPID and try again.

Question 3

What are the hepatic monitoring recommendations during the first year of treatment with JUXTAPID?

- a. Check transaminases only if the patient experiences signs and symptoms of liver injury.
- b. Monitor transaminase levels every 3 months.**
- c. Monitor ALT and AST (at a minimum) prior to what ever occurs first.



Incorrect

During the first year of therapy transaminases should be monitored every 30 days or prior to each increase in dose.

At a minimum ALT and AST should be checked every 30 days.

Review the [Hepatic Monitoring Recommendations](#) for JUXTAPID and try again

Question 3

What are the hepatic monitoring recommendations during the first year of treatment with JUXTAPID?

- a. Check transaminases only if the patient experiences signs and symptoms of liver injury.
- b. Monitor transaminase levels every 3 months.
- c. **Monitor ALT and AST (at a minimum) prior to each increase in dose, or what ever occurs first.**



Correct!

During the first year of therapy transaminases should be monitored every 30 days or prior to each increase in dose.

At a minimum ALT and AST should be checked every 30 days.

[Click here to advance](#)



Question 4

Jane Smith is 24 years old and has a clinical and laboratory diagnosis of HoFH. She has been on JUXTAPID for 13 months, appears to be compliant with her medication. You want to increase the dose, what should you do before you increase the dose?

- a. Measure AST, ALT, alkaline phosphatase and total bilirubin after the increase in dose.
- b. Increase her dose, see her back in a month.
- c. Measure AST, ALT, alkaline phosphatase and total bilirubin if not performed in the last 30 days and only adjust the dose if normal.



Question 4

Jane Smith is 24 years old and has a clinical and laboratory diagnosis of HoFH. She has been on JUXTAPID for 13 months, appears to be compliant with her medication. You want to increase the dose, what should you do before you increase the dose?

- a. Measure AST, ALT, alkaline phosphatase and t
- b. Increase her dose, see her back in a month.
- c. Measure AST, ALT, alkaline phosphatase and t days and only adjust the dose if normal.



Incorrect

Before you increase Ms. Smith's dose minimally AST and ALT should be measured and confirmed to be within acceptable ranges. Review the options and consider another approach.

Review the [Hepatic Monitoring Recommendations](#) for JUXTAPID and try again

Question 4

Jane Smith is 24 years old and has a clinical and laboratory diagnosis of HoFH. She has been on JUXTAPID for 13 months, appears to be compliant with her medication. You want to increase the dose, what should you do before you increase the dose?

- a. Measure AST, ALT, alkaline phosphatase and total
- b. Increase her dose, see her back in a month.**
- c. Measure AST, ALT, alkaline phosphatase and total days and only adjust the dose if normal within the



Incorrect

Before you increase Ms. Smith's dose minimally AST and ALT should be measured and confirmed to be within acceptable ranges. Review the options and consider another approach.

Review the [Hepatic Monitoring Recommendations](#) for JUXTAPID and try again

Question 4

Jane Smith is 24 years old and has a clinical and laboratory diagnosis of HoFH. She has been on JUXTAPID for 13 months, appears to be compliant with her medication. You want to increase the dose, what should you do before you increase the dose?

- a. Measure AST, ALT, alkaline phosphatase and total cholesterol
- b. Increase her dose, see her back in a month.
- c. **Measure AST, ALT, alkaline phosphatase and total cholesterol 30 days and only adjust the dose if normal within 30 days**

 Correct!

Before you increase Ms. Smith's dose minimally AST and ALT should be measured and confirmed to be within acceptable ranges.



[Click here to advance](#)



Question 5

Your patient Thomas Jones, who has a clinical and laboratory diagnosis of HoFH presents to your clinic after being on JUXTAPID for 6 months. His ALT is $\geq 5x$ the ULN.

Your next step should be:

- a. Withhold dosing, obtain additional liver related labs and investigate the potential cause.
- b. Repeat the ALT in one week, if still elevated reduce the dose, repeat ALT tests weekly until it is less than 3x ULN.
- c. Decrease the dose of JUXTAPID.
- d. Continue the JUXTAPID for another month and re-measure the ALT.



Question 5

Your patient Thomas Jones, who has a clinical and laboratory diagnosis of HoFH presents to your clinic after being on JUXTAPID for 6 months. His ALT is $\geq 5x$ the ULN.

Your next step should be:

- a. **Withhold dosing, obtain additional liver related laboratories to investigate the potential cause.**
- b. Repeat the ALT in one week, if still elevated weekly until it is less than 3x ULN.
- c. Decrease the dose of JUXTAPID.
- d. Continue the JUXTAPID for another month and recheck ALT.



Correct!

If AST and/or ALT is $\geq 5x$ ULN the dose of JUXTAPID should be withheld, obtain additional liver related laboratories if not already obtained and investigate the potential cause. Withhold dosing until transaminase levels drop below 3X ULN.



[Click here to advance](#)



Question 5

Your patient Thomas Jones, who has a clinical and laboratory diagnosis of HoFH presents to your clinic after being on JUXTAPID for 6 months. His ALT is $\geq 5x$ the ULN.

Your next step should be:

- a. Withhold dosing, obtain additional liver related labs to rule out other potential cause.
- b. Repeat the ALT in one week, if still elevated repeat weekly until it is less than 3x ULN.**
- c. Decrease the dose of JUXTAPID.
- d. Continue the JUXTAPID for another month and recheck ALT.

 **Incorrect**

If AST and/or ALT is $\geq 5x$ ULN the dose of JUXTAPID should be withheld, obtain additional liver related laboratories if not already obtained and investigate the potential cause. Withhold dosing until transaminase levels drop below 3X ULN.

Review the [Hepatic Monitoring Recommendations](#) for JUXTAPID and try again.

Question 5

Your patient Thomas Jones, who has a clinical and laboratory diagnosis of HoFH presents to your clinic after being on JUXTAPID for 6 months. His ALT is $\geq 5x$ the ULN.

Your next step should be:

- a. Withhold dosing, obtain additional liver related labs to identify potential cause.
- b. Repeat the ALT in one week, if still elevated repeat weekly until it is less than 3x ULN.
- c. **Decrease the dose of JUXTAPID.**
- d. Continue the JUXTAPID for another month and recheck ALT.



Incorrect

If AST and/or ALT is $\geq 5x$ ULN the dose of JUXTAPID should be withheld, obtain additional liver related laboratories if not already obtained and investigate the potential cause. Withhold dosing until transaminase levels drop below 3X ULN.

Review the [Hepatic Monitoring Recommendations](#) for JUXTAPID and try again.

Question 5

Your patient Thomas Jones, who has a clinical and laboratory diagnosis of HoFH presents to your clinic after being on JUXTAPID for 6 months. His ALT is $\geq 5x$ the ULN.

Your next step should be:

- a. Withhold dosing, obtain additional liver related labs to investigate potential cause.
- b. Repeat the ALT in one week, if still elevated repeat weekly until it is less than 3x ULN.
- c. Decrease the dose of JUXTAPID.
- d. **Continue the JUXTAPID for another month and re-evaluate.**

Incorrect

If AST and/or ALT is $\geq 5x$ ULN the dose of JUXTAPID should be withheld, obtain additional liver related laboratories if not already obtained and investigate the potential cause. Withhold dosing until transaminase levels drop below 3X ULN.

Review the [Hepatic Monitoring Recommendations](#) for JUXTAPID and try again.

Question 6

Sandra Brown has been on JUXTAPID for 4 months. She presents to your clinic with nausea, vomiting, abdominal pain, jaundice and is feeling “achy all over”.

You check transaminases and the AST is 3x ULN, the ALT is 2 x ULN.

What should you do next?

- a. Discontinue JUXTAPID treatment.
- b. Identify the probable cause.
- c. Follow AST, ALT, total bilirubin and alkaline phosphatase until normal.
- d. All of the above



Question 6

Sandra Brown has been on JUXTAPID for 4 months. She presents to your clinic with nausea, vomiting, abdominal pain, jaundice and is feeling “achy all over”.

You check transaminases and the AST is 3x ULN, the ALT is 2x ULN.

What should you do next?

- a. **Discontinue JUXTAPID treatment.**
- b. Identify the probable cause.
- c. Follow AST, ALT, total bilirubin and alkaline
- d. All of the above.

Partly correct.

Although it is recommended that JUXTAPID treatment is discontinued in patients who experience symptoms of liver injury accompanied by elevations in transaminases. However, there are other actions that should be considered.

Review the [Hepatic Monitoring Recommendations](#) for JUXTAPID and try again.

Question 6

Sandra Brown has been on JUXTAPID for 4 months. She presents to your clinic with nausea, vomiting, abdominal pain, jaundice and is feeling “achy all over”.

You check transaminases and the AST is 3x ULN, the ALT is 2x ULN.

What should you do next?

- a. Discontinue JUXTAPID treatment.
- b. Identify the probable cause.**
- c. Follow AST, ALT, total bilirubin and alkaline phosphatase.
- d. All of the above.

Partly correct.

Although the identification of the possible cause of the elevations in AST and ALT and the symptoms of liver injury is important, there are other actions that should be considered.

Review the [Hepatic Monitoring Recommendations](#) for JUXTAPID and try again.

Question 6

Sandra Brown has been on JUXTAPID for 4 months. She presents to your clinic with nausea, vomiting, abdominal pain, jaundice and is feeling “achy all over”.

You check transaminases and the AST is 3x ULN, the ALT is 2x ULN.

What should you do next?

- a. Discontinue JUXTAPID treatment.
- b. Identify the probable cause.
- c. **Follow AST, ALT, total bilirubin and alkaline**
- d. All of the above.

Partly correct.

Although the AST and ALT are not higher than 3x ULN, the patient is experiencing symptoms accompanied with transaminase elevations. It is also important to follow liver functions until they resolve, however there may be other actions you should take.

Review the [Hepatic Monitoring Recommendations](#) for JUXTAPID and try again.

Question 6

Sandra Brown has been on JUXTAPID for 4 months. She presents to your clinic with nausea, vomiting, abdominal pain, jaundice and is feeling “achy all over”.

You check transaminases and the AST is 3x ULN, the ALT is 2x ULN.

What should you do next?

- a. Discontinue JUXTAPID treatment.
- b. Identify the probable cause.
- c. Follow AST, ALT, total bilirubin and alkaline phosphatase.
- d. **All of the above.**

 **Correct!**

It is recommended that patients who experience elevations in transaminases accompanied by symptoms of liver injury accompanied by, discontinue treatment with JUXTAPID, LFTs should continue to be followed until they resolve, and further investigation should be instituted to identify the probable cause.



[Click here to advance](#)



Question 7

One of the key points in the REMS program is patient education on the risks of hepatotoxicity with JUXTAPID.

- a. True.
- b. False.



Question 7

One of the key points in the REMS program is patient education on the risks of hepatotoxicity with JUXTAPID.

- a. **True.**
- b. False.

Correct!

JUXTAPID is associated with a risk of hepatotoxicity and as a result there is a REMS Program in place to ensure that its benefits outweigh its risks. The REMS Program requires patients to participate in the treatment decision process. This requires the prescriber to review the Guide for Patients with the patient. Knowledge of the appropriate indication for use and the risk of hepatotoxicity is expected to allow them to participate effectively in that process.



Click here to advance



Question 7

One of the key points in the REMS program is patient education on the risks of hepatotoxicity with JUXTAPID.

- a. True.
- b. False.



Incorrect

Review the [goals of the JUXTAPID REMS program](#) and retry this question.

Question 8

How does a prescriber become certified in the JUXTAPID REMS Program?

- a. Complete and submit the JUXTAPID REMS Program Prescriber Enrollment Form
- b. Successfully complete the JUXTAPID REMS Program Prescriber Training Module and Knowledge Assessment
- c. Review the JUXTAPID PI and the JUXTAPID REMS Program Fact Sheet.
- d. All of the above.



Question 8

How does a prescriber become certified in the JUXTAPID REMS program?

- a. **Complete and submit the JUXTAPID REMS Program Prescriber Enrollment Form**
- b. Successfully complete the JUXTAPID REMS Program Prescriber Training Module and Knowledge Assessment
- c. Review the JUXTAPID PI and the JUXTAPID
- d. All of the above.

Almost.

To become a certified prescriber in the JUXTAPID REMS Program you must successfully complete the Prescriber Enrollment Form, Training Module and Knowledge Assessment, and review the PI and REMS Fact Sheet.

Review the [Prescriber Certification Process](#) and try again.

Question 8

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- a. Complete and submit the JUXTAPID REMS Program Prescriber Enrollment Form
- b. Successfully complete the JUXTAPID REMS Prescriber Training Module and Knowledge Assessment**
- c. Review the JUXTAPID PI and the JUXTAPID
- d. All of the above.



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Review the [Prescriber Certification Process](#) and try again.

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- b. Successfully complete the JUXTAPID REMS Program Prescriber Training Module and Knowledge Assessment
- c. **Review the JUXTAPID PI and the JUXTAPID REMS Fact Sheet**
- d. All of the above.

 Almost.

To become a certified prescriber in the JUXTAPID REMS Program you must successfully complete the Prescriber Enrollment Form, Training Module and Knowledge Assessment, and review the PI and REMS Fact Sheet.

Review the [Prescriber Certification Process](#) and try again.

Question 8

How does a prescriber become certified in the JUXTAPID REMS program?

- a. Complete and submit the JUXTAPID REMS Program Prescriber Enrollment Form
- b. Successfully complete the JUXTAPID REMS Program Prescriber Training Module and Knowledge Assessment
- c. Review the JUXTAPID PI and the JUXTAPID
- d. **All of the above.**



Correct!

To become a certified prescriber in the JUXTAPID REMS Program you must successfully complete the prescriber enrollment form, training module and knowledge assessment, and review the PI and REMS Fact Sheet.



[Click here to advance](#)



CONGRATULATIONS!

You have successfully completed the **Prescriber Training Module and Knowledge Assessment**.

Click [here](#) for a copy of your Certificate of Completion

NEXT STEPS

- Complete and sign the **Prescriber Enrollment Form**, and
- Submit the Prescriber Enrollment Form to the JUXTAPID REMS Coordinating Center either by fax: 1-855-898-2498 or email: REMS@amrytpharma.com

If all the certification requirements are met, the JUXTAPID REMS Coordinating center will confirm you are certified as a prescriber in the JUXTAPID REMS Program. Once you are certified in the JUXTAPID REMS Program you can counsel patients on the REMS program requirements and prescribe JUXTAPID.



Note to Reviewer:

The following slides are the “refresher” slides that you are directed to after answering a question incorrectly. These slide are duplicates of the original slide with the exception of the hyperlink back to the question. These slide will not be visible in the training program, unless the participant answers the questions incorrectly.

JUXTAPID REMS Program Goals

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

❶ 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 the product labeling.

❷ JUXTAPID is dispensed only to patients with a clinical or laboratory diagnosis consistent with homozygous familial hypercholesterolemia (HoFH)

and

❸ Patients are informed about the risk of hepatotoxicity associated with the use of JUXTAPID and the need for baseline and periodic monitoring



To retry Question 1 click here



Redirect from Question 2

Indication

JUXTAPID is only 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).

Limitations of use:

- The safety and effectiveness of JUXTAPID have not been established in patients with hypercholesterolemia who do not have HoFH.



To retry Question 2 click here



REMS PROGRAM

Prescriber Training Module and Knowledge Assessment

Monitoring of transaminases

Timing	Liver monitoring recommendations
Prior to initiating JUXTAPID	Alanine aminotransferase (ALT), aspartate aminotransferase (AST), alkaline phosphatase, and total bilirubin
If abnormal, consider initiating JUXTAPID only after an appropriate workup and the baseline abnormalities have been explained or resolved.	
During the first year of treatment	ALT and AST (at a minimum) prior to each increase in dose or monthly, whichever occurs first
After the first year of treatment	ALT and AST (at a minimum) at least every 3 months and before any increase in dose

At any time during treatment

If transaminases are abnormal, reduce or withhold dosing of JUXTAPID and monitor as recommended in the Prescribing Information. Discontinue JUXTAPID for persistent or clinically significant elevations.

If transaminase elevations are accompanied by clinical symptoms of liver injury (such as nausea, vomiting, abdominal pain, fever, jaundice, lethargy, flu-like symptoms), increases in bilirubin $\geq 2x$ ULN, or active liver disease, discontinue treatment with JUXTAPID and identify the probable cause.



Hepatic Monitoring Recommendations

ALT or AST	Treatment and Monitoring Recommendations*
≥3x and <5x ULN	<ul style="list-style-type: none"> Confirm elevation with a repeat measurement within one week. If confirmed, reduce the dose and obtain additional liver-related tests if not already measured (such as alkaline phosphatase, total bilirubin, and INR). Repeat tests weekly and withhold dosing if there are signs of abnormal liver function (increase in bilirubin or INR), if transaminase levels rise above 5x ULN, or if transaminase levels do not fall below 3x ULN within approximately 4 weeks. In these cases of persistent or worsening abnormalities, also investigate to identify the probable cause. If resuming JUXTAPID after transaminases resolve to < 3x ULN, consider reducing the dose and monitor liver-related tests more frequently.
≥5x ULN	<ul style="list-style-type: none"> Withhold dosing, obtain additional liver-related tests if not already measured (such as alkaline phosphatase, total bilirubin, and INR), and investigate to identify the probable cause. If resuming JUXTAPID after transaminases resolve to < 3x ULN, reduce the dose and monitor liver-related tests more frequently.

If transaminase elevations are accompanied by clinical symptoms of liver injury (such as nausea, vomiting, abdominal pain, fever, jaundice, lethargy, flu-like symptoms), increases in bilirubin ≥ 2x ULN, or active liver disease, discontinue treatment with JUXTAPID and investigate to identify the probable cause.

*Recommendations based on an ULN of approximately 30-40 international units/L

[To retry Question 4, click here](#)



Hepatic Monitoring Recommendations Continued from previous slide

ALT or AST	Treatment and Monitoring Recommendations*
≥3x and <5x ULN	<ul style="list-style-type: none"> • Confirm elevation with a repeat measurement within one week. • If confirmed, reduce the dose and obtain additional liver-related tests if not already measured (such as alkaline phosphatase, total bilirubin, and INR). • Repeat tests weekly and withhold dosing if there are signs of abnormal liver function (increase in bilirubin or INR), if transaminase levels rise above 5x ULN, or if transaminase levels do not fall below 3x ULN within approximately 4 weeks. In these cases of persistent or worsening abnormalities, also investigate to identify the probable cause. • If resuming JUXTAPID after transaminases resolve to < 3x ULN, consider reducing the dose and monitor liver-related tests more frequently.
≥5x ULN	<ul style="list-style-type: none"> • Withhold dosing, obtain additional liver-related tests if not already measured (such as alkaline phosphatase, total bilirubin, and INR), and investigate to identify the probable cause. • If resuming JUXTAPID after transaminases resolve to < 3x ULN, reduce the dose and monitor liver-related tests more frequently.

If transaminase elevations are accompanied by clinical symptoms of liver injury (such as nausea, vomiting, abdominal pain, fever, jaundice, lethargy, flu-like symptoms), increases in bilirubin ≥ 2x ULN, or active liver disease, discontinue treatment with JUXTAPID and investigate to identify the probable cause.

*Recommendations based on an ULN of approximately 30-40 international units/L

[To retry Question 5, click here](#)



Hepatic Monitoring Recommendations Continued from previous slide

ALT or AST	Treatment and Monitoring Recommendations*
≥3x and <5x ULN	<ul style="list-style-type: none">• Confirm elevation with a repeat measurement within one week.• If confirmed, reduce the dose and obtain additional liver-related tests if not already measured (such as alkaline phosphatase, total bilirubin, and INR).• Repeat tests weekly and withhold dosing if there are signs of abnormal liver function (increase in bilirubin or INR), if transaminase levels rise above 5x ULN, or if transaminase levels do not fall below 3x ULN within approximately 4 weeks. In these cases of persistent or worsening abnormalities, also investigate to identify the probable cause.• If resuming JUXTAPID after transaminases resolve to < 3x ULN, consider reducing the dose and monitor liver-related tests more frequently.
≥5x ULN	<ul style="list-style-type: none">• Withhold dosing, obtain additional liver-related tests if not already measured (such as alkaline phosphatase, total bilirubin, and INR), and investigate to identify the probable cause.• If resuming JUXTAPID after transaminases resolve to < 3x ULN, reduce the dose and monitor liver-related tests more frequently.

If transaminase elevations are accompanied by clinical symptoms of liver injury (such as nausea, vomiting, abdominal pain, fever, jaundice, lethargy, flu-like symptoms), increases in bilirubin ≥ 2x ULN, or active liver disease, discontinue treatment with JUXTAPID and investigate to identify the probable cause.

*Recommendations based on an ULN of approximately 30-40 international units/L

To retry Question 6 click here



JUXTAPID REMS Program Goals

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

❶ 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 the product labeling.

❷ JUXTAPID is dispensed only to patients with a clinical or laboratory diagnosis consistent with homozygous familial hypercholesterolemia (HoFH)

and

❸ Patients are informed about the risk of hepatotoxicity associated with the use of JUXTAPID and the need for baseline and periodic monitoring.



To retry Question 7 click here



Prescriber Certification Process

① REVIEW the JUXTAPID

- JUXTAPID Prescribing Information
- JUXTAPID REMS Program **Fact Sheet**

② COMPLETE the JUXTAPID REMS Program

- **Prescriber Training Module** and Knowledge Assessment

③ AGREE to:

- Counsel patients using the JUXTAPID REMS Program **Patient Guide**
- Complete, sign and submit the JUXTAPID REMS Program **Patient-Prescriber Acknowledgement Form** with the patient
- Submit a JUXTAPID REMS Program **Prescription Authorization Form** for each prescription

④ SUBMIT to the REMS Coordinating Center the:

- Completed JUXTAPID REMS Program **Prescriber Enrollment Form**



To retry Question 8, click here



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

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 Program.

The goal of the JUXTAPID REMS program 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 monitoring

JUXTAPID REMS Program Requirements

- Certification of prescribers of JUXTAPID
- Patient counseling
- Certification of pharmacies to dispense JUXTAPID
- A valid JUXTAPID REMS Program Prescription Authorization Form signed by a certified prescriber, and
- A completed JUXTAPID REMS Program 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 Juxtapid REMS Program Prescriber Training Module and the Prescriber Enrollment Form. Send the Prescriber Enrollment Form to the Juxtapid REMS Coordinating Center by fax: **1-855-898-2498** or email: **REMS@amrytpharma.com**
- 3. Agree**
 - To counsel each patient on the Juxtapid REMS Program including the indication for use, the risk of hepatotoxicity and the need for monitoring using the Patient Guide
 - To complete a Juxtapid REMS Program Patient-Prescriber Acknowledgement Form with each patient

Prescribers must also fax a Juxtapid REMS Program Prescription Authorization Form for each prescription to the Juxtapid REMS Program.

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 Juxtapid REMS Program Pharmacy Training Module and the Pharmacy Enrollment Form and send it with the Certificate of Completion for the Pharmacy Training Module to the Juxtapid REMS Coordinating Center by fax: **1-855-898-2498** or email: **REMS@amrytpharma.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.

What is JUXTAPID?

JUXTAPID is a prescription medicine used along with a low-fat diet and other cholesterol-lowering treatments, including low-density lipoprotein apheresis where available, to lower different forms of cholesterol in people with homozygous familial hypercholesterolemia (HoFH).

Because of the risk of liver problems, JUXTAPID should only be taken by people with HoFH.

It is not known if JUXTAPID is safe and effective in people with high cholesterol who do not have HoFH, including in people who have heterozygous familial hypercholesterolemia (HeFH).

Risk of liver problems with JUXTAPID

JUXTAPID can cause liver problems such as increased liver enzymes or increased fat in the liver.

Your doctor will order blood tests to check your liver before you start JUXTAPID, if your dose is increased, and while you are taking JUXTAPID.

Blood test results will tell your doctor if certain liver enzyme levels are higher than normal. Enzyme levels higher than normal can be an early sign of liver problems. If your tests show signs of liver problems, your doctor may reduce your dose or stop JUXTAPID altogether.

There are other side effects associated with the use of JUXTAPID. Talk to your doctor about the other risks associated with JUXTAPID.

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

Because of the risk of liver damage with JUXTAPID, the Food and Drug Administration (FDA) has required a special program called a Risk Evaluation and Mitigation Strategy (REMS) for JUXTAPID. The JUXTAPID REMS Program is designed to educate patients and healthcare providers about the appropriate use of JUXTAPID, the risk of liver damage when taking JUXTAPID, and the need for regular monitoring of your liver.

As part of the REMS Program, your doctor will discuss the risks of JUXTAPID with you and give you this Patient Guide.

Both you and your prescriber must sign the attached JUXTAPID REMS Program Patient-Prescriber Acknowledgement Form for you to receive JUXTAPID. Your prescriber will provide a copy of the signed form to the JUXTAPID REMS Program.

The JUXTAPID REMS Program also requires JUXTAPID to be dispensed by a REMS-certified specialty pharmacy. Your doctor will send your prescription to the certified specialty pharmacy, who will contact you if they need further information.



Instructions for Prescribers

The form must be signed by both the prescriber and patient. If the patient is under the age of 18 years, the form must be signed by their parent or legal guardian.* Fax the completed form to the JUXTAPID REMS Program at 1-855-898-2498. Provide a copy of the form to patient.

PATIENT ACKNOWLEDGEMENT

Patient First Name: _____ Middle Initial: _____ Last Name: _____
City: _____ State: _____ Zip: _____

I have received, read, and understand the JUXTAPID REMS Program Patient Guide with my prescriber and I understand that:

- JUXTAPID is used along with diet and other lipid-lowering treatments in people with homozygous familial hypercholesterolemia (HoFH) to reduce:
- LDL ("bad") cholesterol - A protein that carries "bad" cholesterol in the blood (apolipoprotein B)
- Total cholesterol - Non-high-density lipoprotein cholesterol (non-HDL-C)

JUXTAPID may cause serious side effects including liver problems such as increased liver enzymes or increased fat in the liver.

- Because of these side effects, JUXTAPID is only for people with homozygous familial hypercholesterolemia (HoFH).
I will need to have blood tests to check my liver before I start and during JUXTAPID therapy. If my tests show liver problems, my doctor may lower my dose of JUXTAPID or stop it.

Patient Signature: _____ Date: _____

*Parent or Guardian Signature: _____ Date: _____

Parent or Guardian Name: _____

PRESCRIBER ACKNOWLEDGEMENT

Prescriber First Name: _____ Middle Initial: _____ Last Name: _____

Address: _____

City: _____ State: _____ Zip: _____

Office Phone: _____ NPI #: _____

- I have counseled the patient (parent/guardian when appropriate) on the indication and risks of JUXTAPID, including the risk of liver problems, and the need for periodic monitoring.
I have reviewed the JUXTAPID REMS Program Patient Guide with the patient (and parent/guardian when appropriate) and provided a signed copy of this form to the patient.
I discussed all concerns and answered all questions the patient had about treatment with JUXTAPID.

Prescriber Signature: _____ Date: _____



REMS PROGRAM

Prescription Authorization Form

This form must be completed and signed for each JUXTAPID prescription.

PATIENT INFORMATION

First Name: Middle Initial: Last Name:
Address: Date of Birth:
City: State: Zip:

JUXTAPID PRESCRIPTION

Dose: mg po q hs (recommended starting dosage is 5 mg daily). Quantity to dispense: Refills:
Additional Instructions:

PRESCRIBER INFORMATION AND ATTESTATION OF REMS REQUIREMENTS

First Name: Middle Initial: Last Name:
Practice/Facility Name: Office Contact:
Address:
City: State: Zip:
Office Phone: Office Fax:
State License #: NPI #:

- I understand that JUXTAPID is only indicated as an adjunct to a low-fat diet and other lipid-lowering treatments...
I understand that JUXTAPID has not been studied in patients less than 18 years of age.
I affirm that my patient has a clinical or laboratory diagnosis consistent with HoFH.
I attest that I have obtained and will continue to obtain the liver-related tests for this patient as directed in the JUXTAPID Prescribing Information.
- Prior to initiating therapy, measure ALT, AST, alkaline phosphatase, and total bilirubin.
- During the first year, measure liver-related tests (ALT and AST at a minimum) prior to each increase in dose or monthly, whichever comes first.
- After the first year, measure liver-related tests (ALT and AST at a minimum) at least every 3 months and before any increase in dose.
I authorize the JUXTAPID REMS Program to act on my behalf for the limited purposes of transmitting this prescription to the appropriate pharmacy designated by the patient utilizing their benefit plan.

Prescriber Signature: Substitution Permitted Dispense as Written Date

IMPORTANT

REVIEW TO ENSURE ALL FIELDS ARE COMPLETED • FAX TO 1-855-898-2498

If you have any questions, please contact the JUXTAPID REMS Coordinating Center.
Phone: 1-85-JUXTAPID (1-855-898-2743) | Fax: 1-855-898-2498 | www.juxtapidREMSprogram.com

PRESCRIBER ACTION NEEDED

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

Prescriber Action: Recertification Required by 2 July, 2017

Dear Certified Prescriber:

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 prescribers to be recertified in the JUXTAPID REMS Program by 2 July, 2017** by doing the following:

1. **Review:**

- The JUXTAPID Prescribing Information (PI); and **JUXTAPID REMS Program Fact Sheet** (enclosed)

2. **Complete:**

- The revised on-line **JUXTAPID REMS Program Prescriber Training Module and Knowledge Assessment**

3. **Agree:**

- To counsel all patients on the JUXTAPID REMS Program using the **JUXTAPID REMS Program Patient Guide** and
- To complete the **JUXTAPID REMS Program Patient-Prescriber Acknowledgement Form**.

4. **Submit:**

- The **JUXTAPID REMS Program Prescriber Enrollment Form** and the Certificate of Completion for the Prescriber Training Module and Knowledge Assessment to the JUXTAPID REMS Coordinating Center.

***** Prescribers who do not recertify in the JUXTAPID REMS Program by 2 July 2017 will be decertified and will be unable to prescribe 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 1-85-JUXTAPID (1-855-898-2743).

Sincerely,

A handwritten signature in cursive script that reads "Pamela Foulds".

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

Attachments:
JUXTAPID REMS Program Fact Sheet
JUXTAPID Prescribing Information



REMS PROGRAM

[PRESCRIBER](#)
[PHARMACY](#)
[PATIENT](#)

The JUXTAPID® Risk Evaluation and Mitigation Strategy (REMS) Program

A REMS is a strategy to manage known or potential serious risks associated with a drug and is required by the US Food and Drug Administration (FDA) to ensure that the benefits of the drug outweigh its risks.

The JUXTAPID REMS Program was developed with the FDA.

The purpose of the JUXTAPID REMS Program 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
 - The need to monitor patients during treatment with JUXTAPID, as per the product labeling
2. JUXTAPID is dispensed only to patients with a clinical or laboratory diagnosis consistent with homozygous familial hypercholesterolemia
3. Patients are informed about the risk of hepatotoxicity associated with the use of JUXTAPID and the need for baseline and periodic monitoring

Prescriber

All prescribers of JUXTAPID must become certified in the JUXTAPID REMS Program.

The 3-step process for Prescriber Certification is outlined below:

1. **Review** the JUXTAPID Prescribing Information and the JUXTAPID REMS Program Fact Sheet
2. **Complete** the online Prescriber Training Module and Prescriber Enrollment Form
3. **Agree** to counsel each patient using the Patient Guide, and to complete a Patient-Prescriber Acknowledgement Form with each patient

[GO TO PRESCRIBER CERTIFICATION](#)

INDICATIONS AND USAGE

Homozygous Familial Hypercholesterolemia

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 (LDLC), total cholesterol (TC), apolipoprotein B (apo B), and non-high-density lipoprotein cholesterol (non-HDL-C) in patients with homozygous familial hypercholesterolemia (HoFH).

Limitations of Use

- The safety and effectiveness of JUXTAPID have not been established in patients with hypercholesterolemia who do not have HoFH, including those with heterozygous familial hypercholesterolemia (HeFH).
- The effect of JUXTAPID on cardiovascular morbidity and mortality has not been determined.

**For additional information about the JUXTAPID REMS Program,
please call 1-85-JUXTAPID (1-855-898-2743)**



[PRESCRIBER](#)[PHARMACY](#)[PATIENT](#)

Prescriber certification

[BEGIN NOW](#)

To prescribe JUXTAPID[®], healthcare professionals must be certified in the JUXTAPID Risk Evaluation and Mitigation Strategy (REMS) Program.

Prescriber certification is a 3-step process:

- 1. Review**
the **Prescribing Information** and **Fact Sheet**
- 2. Complete**
 - the online **Prescriber Training Module**, including Knowledge Assessment
 - the **Prescriber Enrollment Form**
 - Send the Prescriber Enrollment Form to the JUXTAPID REMS Coordinating Center by fax: 1-855-898-2498 or email: REMS@amrytpharma.com
- 3. Agree**
to counsel each new patient on the risk of hepatotoxicity and the need for baseline and periodic monitoring using the **Patient Guide**.
Complete a **Patient-Prescriber Acknowledgement Form** with each patient

Program materials

-  [PRESCRIBING INFORMATION](#)
-  [FACT SHEET](#)
-  [PRESCRIBER TRAINING MODULE](#)
-  [PATIENT GUIDE AND PATIENT-PRESCRIBER ACKNOWLEDGEMENT FORM](#)
-  [PRESCRIBER ENROLLMENT FORM](#)
-  [PRESCRIPTION AUTHORIZATION FORM](#)

**For additional information about the JUXTAPID REMS Program,
please call 1-85-JUXTAPID (1-855-898-2743)**



[PRESCRIBER](#)[PHARMACY](#)[PATIENT](#)

Pharmacy certification

Prior to beginning certification process, please contact the JUXTAPID REMS Program, 1-85-JUXTAPID (1-855-898-2743) for consideration.

[BEGIN NOW](#)

To purchase and dispense JUXTAPID[®] all pharmacies must be certified in the JUXTAPID Risk Evaluation and Mitigation Strategy (REMS) Program. The pharmacy must identify an **Authorized Representative** to be certified in the JUXTAPID REMS Program. The pharmacy must be recertified if the authorized person changes.

Pharmacy certification is a 3-step process:

- 1. Review**
the **Prescribing Information** and **Fact Sheet**
- 2. Complete**
 - the online **Pharmacy Training Module**, including Knowledge Assessment
 - the **Pharmacy Enrollment Form**
 - Send 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@amrytpharma.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

Program materials

[↓ PRESCRIBING INFORMATION](#)[↓ FACT SHEET](#)[🔗 PHARMACY TRAINING MODULE](#)[↓ PHARMACY ENROLLMENT FORM](#)

**For additional information about the JUXTAPID REMS Program,
please call 1-85-JUXTAPID (1-855-898-2743)**



[PRESCRIBER](#)[PHARMACY](#)[PATIENT](#)

Patient education

Risk of Liver Problems

- JUXTAPID can cause liver problems such as increased liver enzymes or increased fat in the liver.
- Because of the risk of liver problems, JUXTAPID should only be taken by people with homozygous familial hypercholesterolemia (HoFH).
- Your doctor will order blood tests to check your liver before you start taking JUXTAPID, if your dose is increased, and while you are taking JUXTAPID.

The JUXTAPID REMS Program

Because of the risk of liver damage with JUXTAPID, the Food and Drug Administration (FDA) has required a special program called a Risk Evaluation and Mitigation Strategy (REMS).

As part of the REMS Program your prescriber will discuss the risks of JUXTAPID with you, and review the **Patient Guide** to the REMS Program.

After reviewing the JUXTAPID REMS Program, both you and your healthcare provider will be asked to complete a form acknowledging that you understand the risks with the use of JUXTAPID.

Program materials

 [PATIENT GUIDE and
PATIENT-PRESCRIBER
ACKNOWLEDGEMENT FORM](#)

**For additional information about the JUXTAPID REMS Program,
please call 1-85-JUXTAPID (1-855-898-2743)**





REMS PRO

X

In order to complete your enrollment, you must proceed to the secure area of the Juxtapid REMS Program website.

CONTINUE

CANCEL

Prescriber certification

[BEGIN NOW](#)

To prescribe JUXTAPID[®], healthcare professionals must be certified in the JUXTAPID Risk Evaluation and Mitigation Strategy (REMS) Program.

Prescriber certification is a 3-step process:

- 1. Review**
the **Prescribing Information** and **Fact Sheet**
- 2. Complete**
 - the online **Prescriber Training Module**, including Knowledge Assessment
 - the **Prescriber Enrollment Form**
 - Send the Prescriber Enrollment Form to the JUXTAPID REMS Coordinating Center by fax: 1-855-898-2498 or email: REMS@amrytpharma.com
- 3. Agree**
to counsel each new patient on the risk of hepatotoxicity and the need for baseline and periodic monitoring using the **Patient Guide**.
Complete a **Patient-Prescriber Acknowledgement Form** with each patient

BER

PHARMACY

PATIENT

Program materials

[PRESCRIBING INFORMATION](#)[FACT SHEET](#)[PRESCRIBER TRAINING MODULE](#)[PATIENT GUIDE AND
PATIENT-PRESCRIBER
ACKNOWLEDGEMENT FORM](#)[PRESCRIBER ENROLLMENT FORM](#)[PRESCRIPTION
AUTHORIZATION FORM](#)

PRIVACY POLICY

Amryt Pharma Plc, and its subsidiaries, ("Amryt"), respect individual privacy and are committed to protecting personal information in conformity with applicable legal and ethical standards. This Privacy Policy sets forth our practices regarding the collection, use, and disclosure of information that you may provide through this site. Please read this entire Privacy Policy before using this site or submitting information to us through this site. By using this site and whenever you submit information through this site to us, you agree with the terms of this Privacy Policy written below.

We Collect Personal Information

We only collect personal information, such as your name, address, telephone number, or e-mail address, when you voluntarily submit it to us.

Cookies and Other Non-Personal Information

Cookies: We collect information about your usage of our site through cookies and similar technology. There are two types of cookies: session cookies (non-persistent cookies) and persistent cookies. Session cookies temporarily store non-personally identifiable information about your visit to our website in your computer's memory. The cookie is deleted as soon as you close your browser. Persistent or permanent cookies will uniquely identify your browser and will permanently save in your computer's memory information requested by the website. We may also use pixels, or transparent GIF files. These GIF files are provided by our ad management partner. These files would enable our ad management partners to recognize a unique cookie on your Web browser, which in turn would enable us to learn which advertisements bring users to our website.

With both cookies and transparent GIF files, the information that we collect and share is anonymous and not personally identifiable. It does not contain your name, address, telephone number, or e-mail address. **Session Information:** We also track the total number of visitors to our website, the number of visitors to each page of the website, and the domain names of our visitors' Internet service providers. No personal information is gathered in any of these processes.

IP Address: We record the Internet Protocol (IP) address of your computer when you visit our site. We use analysis software to look at IP addresses only for the purpose of enhancing your user experience. This information is not used to develop a personal profile of you and the log files are regularly purged.

In some countries, you will need to log in with DocCheck to access the professional area of this website. For information on how DocCheck uses your data visit <http://info.doccheck.com/com/privacy/>. An encrypted value for validating your DocCheck login is stored in a cookie on your device until your session is closed. Beyond that, we do not store any data when registering via DocCheck. The Service/treatment centres page of this website uses Google-maps and your data will be collected by Google. For more information on the purpose and scope of data collection and processing by Google, please see Google's privacy policy www.google.com/intl/de_en/policies/privacy/. This will also provide you with further information about your rights in this regard and setting options to protect your privacy.

How We Use This Information

We will not sell or share your name or any detailed information about you to independent companies so that those companies can solicit you for the purpose of selling their goods or services. We use the information about your use of the services and activities on our site to monitor user traffic patterns and try to analyze user preferences so that we can better tailor your site experience and customize the information provided to you by us for your specific interests.

Personal Information

You do not have to submit your personal information to access most of the information available to you on our site. However, if you choose to provide such information to us, we may use this information to follow up with you on specific matters or to provide you with information that you may be interested in, to provide you with technical assistance, or to respond to your questions. If you have indicated that you are interested in receiving information about our products and services, we and companies operating on our behalf (see below) may use your data to send you this information or contact you directly. We also may need to send you specific administrative notices about your account, and in some cases, we may need to use the information in order to contact you if required by law.

Cookies and Other Non-Personal Information

Cookies: Cookies allow us to bring you the content and features likely to be of greatest interest to you based on your previous activities on our site. In our sites that require passwords, you are giving us explicit permission to use a "persistent cookie," which is a small data file that is generated when you enter your assigned user ID and password and access the site. This file is saved in your computer's memory and enables your browser to access each page that is in the password-protected area. **IP Address:** In addition to using the IP address of your computer to maintain communications with you as you move about our site, we also may use your IP address to personalize content provided on the site.

How We Disclose Your Information

Our Relationships With Other Third-Party Companies: We may use third-party companies to provide services and information on the site (see the paragraph about vendors and suppliers above). We also may use third-party vendors or agents to analyze data collected on the site. If we allow a third-party contractor to have access to your information, they will only be permitted to take it or use it for purposes that are consistent with this Privacy Policy. In addition, these vendors and agents will have to ensure the confidentiality and security of their information processing and implement adequate measures to protect this information. As required by Law. In certain limited circumstances, we may be called upon to release your personal information in response to a court order, subpoena, search warrant, law, or regulation. We also may need to use your information to contact you if required by law. We plan to cooperate in responding to such requests, taking appropriate measures to ensure that the requester understands the sensitive nature of the information that they may receive. We also reserve the right to cooperate with law enforcement authorities in investigating and prosecuting users who violate our rules or engage in behaviour that is illegal or harmful to other users of the site.

Other Disclosures: Other than as disclosed in this Privacy Policy, we will not use or disclose any personally identifying information you have provided to us to an unrelated third party without your consent.

Your Privacy Choices

Personal Information

If, at any time, you wish to stop receiving e-mails or other communications from us, or if you have submitted personal information through our site and would like to have that information deleted from our records, please notify us. You may also request access to personal data about you that we hold, and you may have the opportunity to request a correction or amendment to your personal data. Notify us directly at dpo@amrytpharma.com As a reminder to you when exchanging e-mails, any e-mail that you send or receive on your employer's e-mail system may be the property of your employer. Consequently, your employer may have the ability to review your personal information sent via e-mail. Please note that although we attempt to adhere to requests to remove personal data from our records, it may not be possible to remove all copies depending on the manner in which the information was submitted to us. In addition, we reserve the right to not remove or amend information provided to us regarding an adverse drug effect, and information is otherwise required to be retained by law.

Cookies and Other Non-Personal Information

Your Web browser can be set to allow you to control whether you will accept cookies, reject cookies, or to notify you each time a cookie is sent to you. If your browser is set to reject cookies, sites like ours that are cookie-enabled will not recognize you when you return to the site and some site functionality may be lost.

Notice About Internet Security

While we make every reasonable effort to protect the information collected through its websites, including this site, please be aware that there is always some risk involved when submitting data over the Internet. We cannot guarantee that our website is 100% safe from illegal tampering or "hacking." Any data transmitted over the Internet may be at risk; however, once it is received by us and entered into our database, it has the same protection that we extend to its own confidential information.

Links to Third-Party Sites

As a convenience to our visitors, our site currently contains links to a number of other sites that we believe may offer useful information. The Privacy Policy does not apply to those sites. These links are not under our control, and we are not responsible for the content of, or potential damage caused by, any hyperlinked sites. The inclusion of any link on an Amryt site does not indicate or imply any endorsement by Amryt of the hyperlinked sites. You should contact these sites directly for information on their privacy policies, confidentiality agreements, and data collection/distribution procedures. Please note that linked sites may also use cookies. We cannot control the use of cookies by these sites. In addition, when you link from our website to another website, that site may have the ability to recognize that you have come from our site. If you do not want any other websites to know that you have been on this website, we recommend that you do not use the links provided in our site.

Children's Policy

The site content and services are intended for adult users over the age of 13. The site is not designed to attract underage users. If we learn that an under-13 user has provided personal information, we will delete such information from our active databases.

Privacy Policy Updates

We will only use personal information in the manner described in the Privacy Policy in effect when the information was collected from you. However, we reserve the right to change the terms of this Privacy Policy at any time by posting revisions to the site. This privacy policy was last updated May 2020.

**For additional information about the JUXTAPID REMS Program,
please call 1-85-JUXTAPID (1-855-898-2743)**

TERMS OF USE

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**For additional information about the JUXTAPID REMS Program,
please call 1-85-JUXTAPID (1-855-898-2743)**



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REMS PROGRAM

[PRESCRIBER](#)

[PHARMACY](#)

[PATIENT](#)

Amryt Pharmaceuticals DAC

45 Mespil Road
Dublin 4, Ireland
+353 1 518 0200

To contact the Amryt Pharma Group in the US, please call (617) 500-7867

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Note to Reviewer:

The Juxtapid REMS Pharmacy Training and Knowledge Assessment can be accessed online by clicking the link on the website. The participant will need to register to enter the training and knowledge assessment module. The registration page requires the participant to indicate that they are an authorized representative of the pharmacy.

Participants will be required to enter their name, pharmacy name, city, state and zip code. The participant's email address will be requested; if this is not provided the participant will be able to continue. These items will be used to generate a Certificate of Completion at the end of the program that will be required to be submitted to enroll the pharmacy in the JUXTAPID REMS program.



JUXTAPID®

Risk Evaluation and Mitigation Strategy (REMS) Program

PHARMACY TRAINING MODULE and KNOWLEDGE ASSESSMENT

This interactive tool:

- Provides an overview of the JUXTAPID REMS Program
- Discusses the risk of hepatotoxicity with JUXTAPID, and
- Provides an overview of the prescriber, patient and pharmacy requirements for the JUXTAPID REMS program



User Guide

To become certified to purchase, dispense and distribute JUXTAPID all pharmacies must:

- Designate an **Authorized Representative** who must:
 - **Successfully** complete this **Pharmacy Training Module & Knowledge Assessment** and print the **Certificate of Completion** at the end of the module
 - **Submit** the Certificate of Completion and the signed JUXTAPID REMS Program **Pharmacy Enrollment Form** to the JUXTAPID REMS Coordinating Center
either by fax: 1-855-898-2498 or email: REMS@amrytpharma.com

At the end of the training module there is a Knowledge Assessment with interactive questions that you must pass. If your answer is incorrect you will be directed back to the relevant page in the materials and will be required to re-answer the question.

This Pharmacy training module and knowledge assessment is intended to be read in conjunction with the JUXTAPID REMS Factsheet and the JUXTAPID Prescribing Information.

This program is expected to take **10-15** minutes.

Click here to begin



REMS PROGRAM

Pharmacy Training Module and Knowledge Assessment



Contents

- Overview of the JUXTAPID REMS Program
- Key JUXTAPID Product Information
- JUXTAPID REMS Program Information
- Knowledge Assessment





Contents

- Overview of the JUXTAPID REMS Program**
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Overview

Because of the risk of hepatotoxicity with JUXTAPID, it is only available through a restricted program called the “JUXTAPID Risk Evaluation and Mitigation Strategy (REMS) Program”.

The purpose of this training module is to educate pharmacy representatives about the JUXTAPID REMS Program including the requirements for prescribers and pharmacies.



A Risk Evaluation and Mitigation Strategy is a strategy to manage known or potential serious risks associated with a drug product and is required by the Food and Drug Administration (FDA) for some products to ensure that the benefits of the drug outweigh its risks.





JUXTAPID REMS Program Goals

The aim of the JUXTAPID REMS Program 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 the product labeling.

② JUXTAPID is dispensed only to patients with a clinical or laboratory diagnosis consistent with homozygous familial hypercholesterolemia (HoFH)

and

③ Patients are informed about the risk of hepatotoxicity associated with the use of JUXTAPID and the need for baseline and periodic monitoring.





Contents

- Overview of the JUXTAPID REMS Program
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Indication

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).

Limitations of use Related to the REMS:

- The safety and effectiveness of JUXTAPID have not been established in patients with hypercholesterolemia who do not have HoFH, including those with heterozygous familial hypercholesterolemia (HeFH).

✦
Please see JUXTAPID full Prescribing Information for the limitations to use, and the **BOXED WARNING** on hepatotoxicity as included on www.juxtapidREMSprogram.com





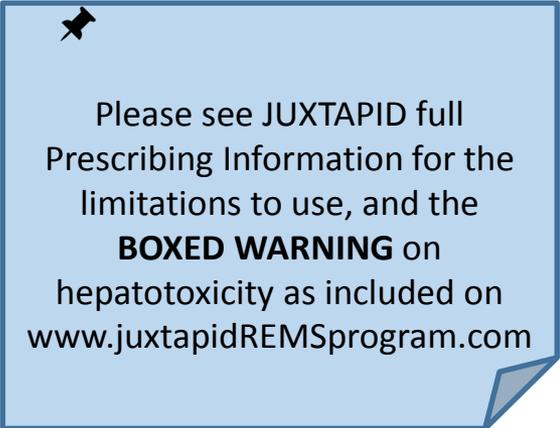
Appropriate Patient Selection

JUXTAPID is only indicated for use in patients with HoFH.

- Patients must have a clinical or laboratory diagnosis consistent with HoFH.

Related Contraindications:

- **Moderate or severe hepatic impairment or active liver disease** including unexplained persistent abnormal liver function tests.



Please see JUXTAPID full Prescribing Information for the limitations to use, and the **BOXED WARNING** on hepatotoxicity as included on www.juxtapidREMSprogram.com





Boxed Warning – Risk of Hepatotoxicity

JUXTAPID can cause elevations in transaminases. In the JUXTAPID clinical trial, 10 (34%) of the 29 patients treated with Juxtapid had at least one elevation in alanine aminotransferase (ALT) or aspartate aminotransferase (AST) $\geq 3x$ upper limit of normal (ULN). There were no concomitant clinically meaningful elevations of total bilirubin, international normalized ratio (INR), or alkaline phosphatase.

JUXTAPID also increases hepatic fat, with or without concomitant increases in transaminases. The median absolute increase in hepatic fat was 6% after both 26 and 78 weeks of treatment, from 1% baseline, measured by magnetic resonance spectroscopy. Hepatic steatosis associated with JUXTAPID treatment may be a risk factor for progressive liver disease, including steatohepatitis and cirrhosis.

Measure ALT, AST, alkaline phosphatase, and total bilirubin before initiating treatment and then ALT and AST regularly as recommended. During treatment adjust dose of JUXTAPID if the ALT or AST are $\geq 3x$ ULN. Discontinue JUXTAPID for clinical significant liver toxicity.

✦
Please see JUXTAPID full Prescribing Information including the full **BOXED WARNING** as included on www.juxtapidREMSprogram.com



REMS PROGRAM

Pharmacy Training Module and Know



Risk of Hepatotoxicity: JUXTAPID can Cause Elevations in Transaminases

Although cases of hepatic failure have not been reported, there is concern that JUXTAPID could induce steatohepatitis, which can progress to cirrhosis over several years.

Elevations in transaminases (alanine aminotransferase [ALT] and/or aspartate aminotransferase [AST]) are associated with JUXTAPID. In the clinical trial, 10 (34%) of the 29 patients with HoFH had at least one elevation in ALT or AST $\geq 3x$ ULN, and 4 (14%) of the patients had at least one elevation in ALT or AST $\geq 5x$ ULN. There were no concomitant or subsequent clinically meaningful elevations in bilirubin, INR, or alkaline phosphatase

If transaminase elevations are accompanied by clinical symptoms of liver injury, such as nausea, vomiting, abdominal pain, fever, jaundice, lethargy, flu-like symptoms, increases in bilirubin $\geq 2x$ ULN, or active liver disease, discontinue treatment with JUXTAPID and identify the probable cause.

Continued next slide





Risk of Hepatotoxicity

JUXTAPID Increases Hepatic Fat

Continued from previous slide

JUXTAPID increases hepatic fat, with or without concomitant increases in transaminases.

The median absolute increase in hepatic fat was 6% after both 26 and 78 weeks of treatment, from 1% baseline, measured by magnetic resonance spectroscopy. Hepatic steatosis associated with JUXTAPID treatment may be a risk factor for progressive liver disease, including steatohepatitis and cirrhosis.

Clinical data suggest that hepatic fat accumulation is reversible after stopping treatment with JUXTAPID, but whether histological sequelae remain is unknown.

Continued next slide



REMS PROGRAM

Pharmacy Training Module and Knowledge Assessment



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REMS PROGRAM

Pharmacy Training Module and Knowledge Assessment



JUXTAPID REMS Program Goals

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

❶ 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 the product labeling.

❷ JUXTAPID is dispensed only to patients with a clinical or laboratory diagnosis consistent with homozygous familial hypercholesterolemia (HoFH)

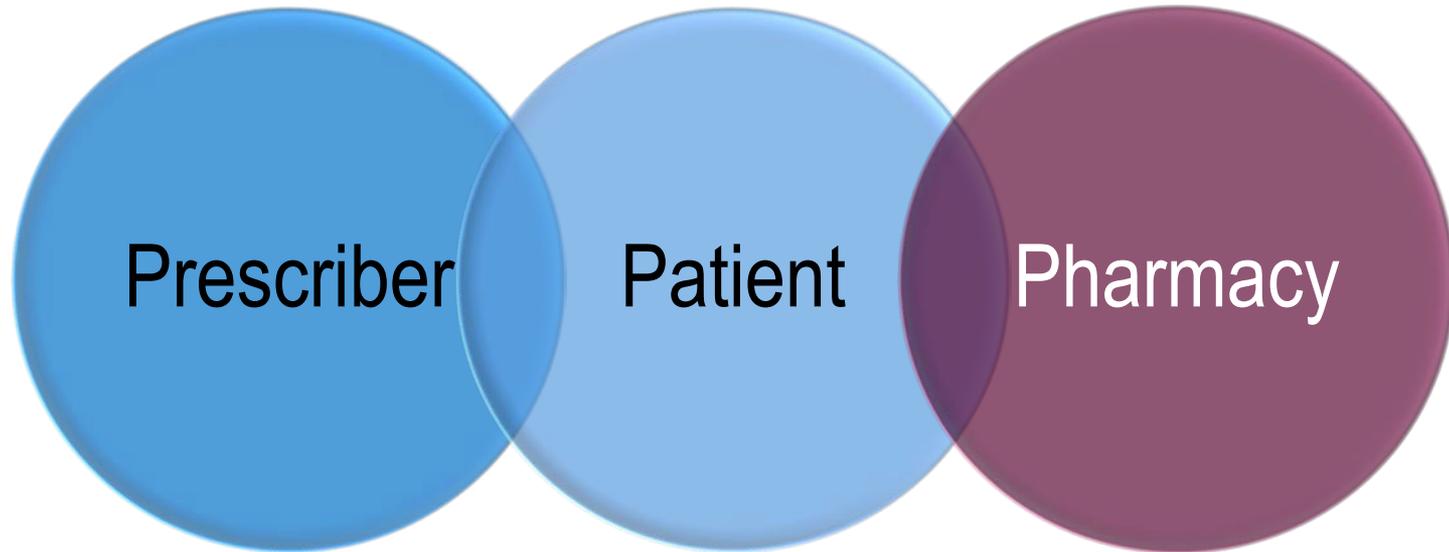
and

❸ Patients are informed about the risk of hepatotoxicity associated with the use of JUXTAPID and the need for baseline and periodic monitoring.





JUXTAPID REMS Key Elements



Prescribers must be certified to prescribe JUXTAPID

Patients must undergo education about the REMS program the approved indication for use the risk of hepatotoxicity with JUXTAPID and the need for regular monitoring

Pharmacies must be certified to distribute and dispense JUXTAPID





Patient-Prescriber Acknowledgment

To enable **patient participation** in the treatment decision process both patients and prescribers are required to review and complete the patient-prescriber acknowledgement form. This form is attached to the Guide for Patients and must be submitted to the JUXTAPID REMS Coordinating Center for all new patients.

THE PRESCRIBER:

① **REVIEWS** the

- **JUXTAPID REMS Program Patient Guide** with the patient.

This document provides a summary of JUXTAPID and the REMS program requirements.

② **COMPLETES** the:

- **JUXTAPID REMS Program Patient-Prescriber Acknowledgement Form (PPAF)**

The PPAF is signed by both the patient and the prescriber and acknowledges that the patient has received education on the JUXTAPID REMS program, understands the hepatic risk and the need for regular monitoring.

Prescriptions will not be dispensed without a completed PPAF on record



REMS PROGRAM

Pharmacy Training Module and Knowledge Assessment

Pharmacy Certification Process



REMS PROGRAM

Pharmacy Training Module and Knowledge Assessment



Authorized Representative Requirements

For a Pharmacy to be certified in the JUXTAPID REMS Program, the pharmacy must designate an Authorized Representative (AR).

The Authorized Representative is required to:

- **Complete** the **pharmacy training module** and knowledge assessment,
- **Oversee** the **conduct of the JUXTAPID REMS** at the pharmacy,
- **Agree** to put **processes** in place, and to **train** applicable pharmacy staff on the JUXTAPID REMS program requirements.

The pharmacy must confirm the name of the authorized representative every year, and advise the REMS Coordinating Center promptly of any change in the AR. If the AR changes, the Pharmacy must recertify within 30 days.





Pharmacy Certification Process

The Authorized Representative must:

① **REVIEW** the

- JUXTAPID **Prescribing Information (PI)**
- JUXTAPID REMS Program **Fact Sheet**

② **COMPLETE** the:

- JUXTAPID REMS Program **Pharmacy Training Module** and Knowledge Assessment

③ **AGREE** to:

- Train all applicable pharmacy staff on the JUXTAPID REMS program requirements.
- Implement processes and procedures to ensure that the requirements of the REMS are met
- Be audited.
- Provide prescription records to Amryt.

④ **SUBMIT** to the REMS Coordinating Center the:

- **Certificate of Completion** for the Pharmacy Training & Knowledge Assessment.
- Completed JUXTAPID REMS Program **Pharmacy Enrollment Form**.





The Pharmacy Must Agree to put Procedures in Place to Verify Prior to Dispensing:

- 1 The **Prescriber is Certified.**
- 2 There is a completed and signed **JUXTAPID REMS Program Patient-Prescriber Acknowledgement Form** for the patient.
- 3 The JUXTAPID REMS Program **Prescription Authorization Form** is completed.





Where do I find the REMS Program Materials?

All JUXTAPID REMS Program materials can be found on the JUXTAPID REMS Program website:

www.juxtapidREMSprogram.com

REMS Materials can also be requested by contacting the JUXTAPID REMS Coordinating Center at:

 1- 855-898-2743



REMS PROGRAM

Pharmacy Training Module and Knowledge Assessment

Knowledge Assessment



REMS PROGRAM

Pharmacy Training Module and Knowledge Assessment



Question 1

The goals of the JUXTAPID REMS program are:

(check the answer that is the most inclusive)

- To educate prescribers about the risk of hepatotoxicity with the use of JUXTAPID.
- To restrict the use of JUXTAPID to only those patients with a clinical and laboratory diagnosis of HoFH.
- To ensure both prescribers and patients understand the risk of hepatotoxicity with JUXTAPID and the need for monitoring of liver function.
- All of the above.





Question 1

The goals of the JUXTAPID REMS program are:

(check the answer that is the most inclusive)

- To educate prescribers about the risk of hepatotoxicity with the use of JUXTAPID.
- To restrict the use of JUXTAPID to only those patients with a diagnosis of HoFH.
- To ensure both prescribers and patients understand the risks of JUXTAPID and the need for monitoring of liver function.
- All of the above.



Partly correct

The education of prescribers about the risk of hepatotoxicity with the use of JUXTAPID is a key part of the JUXTAPID REMS Program. However, there are other goals too. Review the [REMS Program goals](#) and try again.





Question 1

The goals of the JUXTAPID REMS program are:

(check the answer that is the most inclusive)

- To educate prescribers about the risk of hepatotoxicity with the use of JUXTAPID.
- To restrict the use of JUXTAPID to only those patients with a clinical or laboratory diagnosis of HoFH.**
- To ensure both prescribers and patients understand the risks of JUXTAPID and the need for monitoring of liver function.
- All of the above.



Partly correct

The restriction of the use of JUXTAPID to patients with a clinical or laboratory diagnosis of HoFH is a key part of the JUXTAPID REMS Program. However, there are other goals too. Review the [REMS Program goals](#) and try again.



Question 1

The goals of the JUXTAPID REMS program are:

(check the answer that is the most inclusive)

- To educate prescribers about the risk of hepatotoxicity with the use of JUXTAPID.
- To restrict the use of JUXTAPID to only those patients with a diagnosis of HoFH.
- To ensure both prescribers and patients understand JUXTAPID and the need for monitoring of liver function tests.**
- All of the above.



Partly correct

The education of both prescribers and patients about the risk of hepatotoxicity with JUXTAPID and the need for monitoring is an important part of the JUXTAPID REMS Program. However, there are other goals. Review the [REMS Program goals](#) and try again



Question 1

The goals of the JUXTAPID REMS program are:

(check the answer that is the most inclusive)

- To educate prescribers about the risk of hepatotoxicity with the use of JUXTAPID.
- To restrict the use of JUXTAPID to only those patients with a diagnosis of HoFH.
- To ensure both prescribers and patients understand the risks of JUXTAPID and the need for monitoring of liver function.
- All of the above.**



Correct!

All three are goals of the JUXTAPID REMS Program.

Click here to advance





Question 2

Which conditions are appropriate for the use of JUXTAPID?

- a. Mixed dyslipidemia.
- b. Homozygous familial hypercholesterolemia (HoFH).
- c. Heterozygous familial hypercholesterolemia (HeFH).
- d. All of the above.





Question 2

Which conditions are appropriate for the use of JUXTAPID?

- a. Mixed dyslipidemia.
- b. Homozygous familial hypercholesterolemia (HoFH).
- c. Heterozygous familial hypercholesterolemia (HeFH).
- d. All of the above.



Incorrect

JUXTAPID is indicated for use in patients with homozygous familial hypercholesterolemia (HoFH).

Review the [Indication](#) for JUXTAPID and try again



Question 2

Which conditions are appropriate for the use of JUXTAPID?

- a. Mixed dyslipidemia.
- b. Homozygous familial hypercholesterolemia (HoFH).**
- c. Heterozygous familial hypercholesterolemia (HeFH)
- d. All of the above.

 Correct!

JUXTAPID is indicated for use 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).

[Click here to advance](#)





Question 2

Which conditions are appropriate for the use of JUXTAPID?

- a. Mixed dyslipidemia
- b. Homozygous familial hypercholesterolemia (HoFH)
- c. Heterozygous familial hypercholesterolemia (HeFH)**
- d. All of the above



Incorrect

JUXTAPID is indicated for use in patients with homozygous familial hypercholesterolemia (HoFH).

Review the [Indication](#) for JUXTAPID and try again



Question 2

Which conditions are appropriate for the use of JUXTAPID?

- a. Mixed dyslipidemia.
- b. Homozygous familial hypercholesterolemia (HoFH).
- c. Heterozygous familial hypercholesterolemia (HeFH).
- d. All of the above.**



Incorrect

JUXTAPID is indicated for use in patients with homozygous familial hypercholesterolemia (HoFH).

Review the [Indication](#) for JUXTAPID and try again



Question 3

One of the key points in the REMS program is patient education on the risks of hepatotoxicity with JUXTAPID.

- a. True
- b. False





Question 3

One of the key points in the REMS program is patient education on the risks of hepatotoxicity with JUXTAPID.

- a. True
- b. False



Correct!

JUXTAPID is associated with a risk of hepatotoxicity and as a result there is a REMS Program in place to ensure that its benefits outweigh its risks. The REMS Program requires patients to participate in the treatment decision process. Knowledge of the risk of hepatotoxicity is expected to allow them to participate effectively in that process.



[Click here to advance](#)





Question 3

One of the key points in the REMS program is patient education on the risks of hepatotoxicity with JUXTAPID.

- a. True
- b. **False**



Incorrect

Review the [goals of the JUXTAPID REMS program](#) and retry this question.



Question 4

How does a pharmacy become certified in the JUXTAPID REMS program?

- a. Complete and submit the JUXTAPID REMS Program Pharmacy Enrollment Form.
- b. Successfully complete the JUXTAPID REMS Program Pharmacy Training Module and Knowledge Assessment and then submit the Certificate of Completion.
- c. Review the JUXTAPID PI and the JUXTAPID REMS Program Factsheet.
- d. Assign an authorized representative.
- e. All of the above.



REMS PROGRAM

Pharmacy Training Module and Knowledge Assessment



Question 4

How does a pharmacy become certified in the JUXTAPID REMS program?

- a. **Complete and submit the JUXTAPID REMS P Form.**
- b. Successfully complete the JUXTAPID REMS P and Knowledge Assessment and then submit
- c. Review the JUXTAPID PI and the JUXTAPID R
- d. Assign an authorized representative.
- e. All of the above.

Partly Correct.

To become a certified pharmacy in the JUXTAPID REMS Program you must assign an authorized representative for the pharmacy, who completes the enrollment form, training module and knowledge assessment, and reviews the JUXTAPID PI and JUXTAPID REMS Program Factsheet. The Authorized Representative must agree on behalf of the pharmacy to put processes and procedures in place and to train the pharmacy staff on the JUXTAPID REMS Program.

Review the [Pharmacy Certification Process](#) and try again.



Question 4

How does a pharmacy become certified in the JUXTAPID REMS program?

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- b. Successfully complete the JUXTAPID REMS Program Training Module and Knowledge Assessment and then submit the JUXTAPID REMS Program Enrollment Form.**
- c. Review the JUXTAPID PI and the JUXTAPID REMS Program Factsheet.
- d. Assign an authorized representative.
- e. All of the above.

Partly Correct

To become a certified pharmacy in the JUXTAPID REMS Program you must assign an authorized representative for the pharmacy, who completes the enrollment form, training module and knowledge assessment, and reviews the JUXTAPID PI and JUXTAPID REMS Program Factsheet. The Authorized Representative must agree on behalf of the pharmacy to put processes and procedures in place and to train the pharmacy staff on the JUXTAPID REMS Program.

Review the [Pharmacy Certification Process](#) and try again.



Question 4

How does a pharmacy become certified in the JUXTAPID REMS program?

- a. Complete and submit the JUXTAPID REMS
- b. Successfully complete the JUXTAPID REMS and Knowledge Assessment and then submit
- c. **Review the JUXTAPID PI and the JUXTAPID**
- d. Assign an Authorized Representative.
- e. All of the above.

Partly Correct

To become a certified pharmacy in the JUXTAPID REMS Program you must assign an authorized representative for the pharmacy, who completes the enrollment form, training module and knowledge assessment, and reviews the JUXTAPID PI and JUXTAPID REMS Program Factsheet. The Authorized Representative must agree on behalf of the pharmacy to put processes and procedures in place and to train the pharmacy staff on the JUXTAPID REMS Program.

Review the [Pharmacy Certification Process](#) and try again.



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How does a pharmacy become certified in the JUXTAPID REMS program?

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- b. Successfully complete the JUXTAPID REMS and Knowledge Assessment and then submit.
- c. Review the JUXTAPID PI and the JUXTAPID REMS Program Factsheet.
- d. Assign an Authorized Representative.**
- e. All of the above.

Partly Correct

To become a certified pharmacy in the JUXTAPID REMS Program you must assign an authorized representative for the pharmacy, who completes the enrollment form, training module and knowledge assessment, and reviews the JUXTAPID PI and JUXTAPID REMS Program Factsheet. The Authorized Representative must agree on behalf of the pharmacy to put processes and procedures in place and to train the pharmacy staff on the JUXTAPID REMS Program.

Review the [Pharmacy Certification Process](#) and try again.



Question 4

How does a pharmacy become certified in the JUXTAPID REMS program?

- a. Complete and submit the JUXTAPID REMS Program Pharmacy Enrollment Form.
- b. Successfully complete the JUXTAPID REMS Program Pharmacy Training Module and Knowledge Assessment and then submit the Certification of Compliance.
- c. Review the JUXTAPID PI and the JUXTAPID REMS Program Factsheet.
- d. Assign an Authorized Representative.
- e. **All of the above.**

Correct!

To become a certified pharmacy in the JUXTAPID REMS Program you must assign an authorized representative for the pharmacy, who completes the enrollment form, training module and knowledge assessment, and reviews the JUXTAPID PI and JUXTAPID REMS Program Factsheet. The Authorized Representative must agree on behalf of the pharmacy to put processes and procedures in place and to train the pharmacy staff on the JUXTAPID REMS Program

[Click here to advance](#)





Question 5

What is not a requirement of the Authorized Pharmacy Representative?

- a) Review the Juxtapid REMS Program Fact Sheet
- b) Oversee the conduct of the Juxtapid REMS at the Pharmacy
- c) Complete the Juxtapid REMS Program Patient-Prescriber Acknowledgement Form
- d) Put processes and procedures in place to ensure the Juxtapid REMS Program requirements are met





Question 5

What is not a requirement of the Authorized Pharmacy Representative?

- a) Review the JUXTAPID Prescribing Information and the JUXTAPID REMS Program Fact Sheet
- b) Oversee the conduct of the JUXTAPID REMS at the pharmacy
- c) Complete the JUXTAPID REMS Program Patient-Practitioner Acknowledgement Form
- d) Put processes and procedures in place to ensure the REMS requirements are met

Incorrect.

The Authorized Representative of the Pharmacy is required to review the JUXTAPID REMS Program Factsheet and Prescribing Information, oversee the conduct of the REMS, and to put processes and procedures in place to ensure the REMS requirements are met at the pharmacy.

The Prescriber and the Patient must complete the Patient-Practitioner Acknowledgement Form, which must be kept on file for all patients.

Review the [Authorized Representative Requirements](#) and try again.



Question 5

What is not a requirement of the Authorized Pharmacy Representative?

- a) Review the JUXTAPID Prescribing Information and the JUXTAPID REMS Program Fact Sheet
- b) Oversee the conduct of the JUXTAPID REMS at the pharmacy**
- c) Complete the JUXTAPID REMS Program Patient-Practitioner Acknowledgement Form
- d) Put processes and procedures in place to ensure the REMS requirements are met

Incorrect.
The Authorized Representative of the Pharmacy is required to review the JUXTAPID REMS Program Factsheet and Prescribing Information, oversee the conduct of the REMS, and to put processes and procedures in place to ensure the REMS requirements are met at the pharmacy.

The Prescriber and the Patient must complete the Patient-Practitioner Acknowledgement Form, which must be kept on file for all patients.

Review the [Authorized Representative Requirements](#) and try again.





Question 5

What is not a requirement of the Authorized Pharmacy Representative?

- a) Review the JUXTAPID Prescribing Information and the JUXTAPID REMS Program Fact Sheet
- b) Oversee the conduct of the JUXTAPID REMS at the pharmacy
- c) Complete the JUXTAPID REMS Program Patient-Practitioner Acknowledgement Form**
- d) Put processes and procedures in place to ensure all regulatory requirements are met



Correct!

The Prescriber and the Patient must complete the Patient-Practitioner Acknowledgement Form, not the pharmacy authorized representative, however, the Patient-Practitioner Acknowledgement form must be kept on file at the pharmacy for all patients.

Click here to advance



Question 5

What is not a requirement of the Authorized Pharmacy Representative?

- a) Review the JUXTAPID Prescribing Information and the JUXTAPID REMS Program Fact Sheet
- b) Oversee the conduct of the JUXTAPID REMS Program
- c) Complete the JUXTAPID REMS Program Patient Acknowledgement Form
- d) **Put processes and procedures in place to ensure the REMS requirements are met**

 **Incorrect.**

The Authorized Representative of the Pharmacy is required to review the JUXTAPID REMS Program Factsheet and Prescribing Information, oversee the conduct of the REMS, and to put processes and procedures in place to ensure the REMS requirements are met at the pharmacy.

The Prescriber and the Patient must complete the Patient-Prescriber Acknowledgement Form, which must be kept on file for all patients.

Review the [Authorized Representative Requirements](#) and try again.



CONGRATULATIONS!

You have successfully completed the Pharmacy Representative Training Module and Knowledge Assessment.

Click [here](#) for a copy of your Certificate of Completion

NEXT STEPS

- Obtain the **Certificate of Completion** for the Pharmacy Training & Knowledge Assessment
- Complete and sign the **Pharmacy Enrollment Form**, and
- Submit both documents to the JUXTAPID REMS Coordinating Center either by fax: 1-855-898-2498 or email: REMS@amrytpharma.com

If all the certification requirements are met, the JUXTAPID REMS Coordinating center will confirm you are certified as a pharmacy in the JUXTAPID REMS Program.



REMS PROGRAM

Pharmacy Training Module and Knowledge Assessment

Note to Reviewer:

The following slides are the “refresher” slides that you are directed to after answering a question incorrectly. These slide are duplicates of the original slide with the exception of the hyperlink back to the question. These slide will not be visible in the training program, unless the participant answers the questions incorrectly.



JUXTAPID REMS Program Goals

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

❶ 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 the product labeling.

❷ JUXTAPID is dispensed only to patients with a clinical or laboratory diagnosis consistent with homozygous familial hypercholesterolemia (HoFH)

and

❸ Patients are informed about the risk of hepatotoxicity associated with the use of JUXTAPID and the need for baseline and periodic monitoring

To retry Question 1 click here





Redirect from Question 2

Indication

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).

Limitations of use:

- The safety and effectiveness of JUXTAPID have not been established in patients with hypercholesterolemia who do not have HoFH.



To retry Question 2 click here



REMS PROGRAM

Pharmacy Training Module and Knowledge Assessment



Redirect from Question 3

JUXTAPID REMS Program Goals

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

❶ 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 the product labeling.

❷ JUXTAPID is dispensed only to patients with a clinical or laboratory diagnosis consistent with homozygous familial hypercholesterolemia (HoFH)

and

❸ Patients are informed about the risk of hepatotoxicity associated with the use of JUXTAPID and the need for baseline and periodic monitoring.

To retry Question 3 click here





Pharmacy Certification Process

1 REVIEW the

- JUXTAPID Prescribing Information (PI)
- JUXTAPID REMS Program Fact Sheet

2 COMPLETE the:

- JUXTAPID REMS Program Pharmacy Training Module and Knowledge Assessment

3 AGREE to:

- Train all applicable pharmacy staff on the JUXTAPID REMS program requirements
- Implement processes and procedures to ensure that the requirements of the REMS are met
- Be audited.
- Provide prescription records to Amryt.

4 SUBMIT to the REMS Coordinating Center the:

- Certificate of Completion for the Pharmacy Training & Knowledge Assessment
- Completed JUXTAPID REMS Program Pharmacy Enrollment Form

For a Pharmacy to be Certified the Pharmacy must designate an Authorized Representative (AR) who will be required to complete the pharmacy training module and knowledge assessment, oversee the conduct of the REMS at the pharmacy and agree to put processes in place and to train applicable pharmacy staff on the REMS program requirements.

The Pharmacy must confirm the name of the authorized representative every year, and advise the REMS coordinating center promptly of any change in the AR. If the AR changes, the Pharmacy must recertify within 30 days.

To retry Question 4 click here





Authorized Representative Requirements

For a Pharmacy to be certified in the JUXTAPID REMS Program, the pharmacy must designate an Authorized Representative (AR).

The Authorized Representative is required to:

- **Complete** the **pharmacy training module** and knowledge assessment,
- **Oversee** the **conduct of the JUXTAPID REMS** at the pharmacy,
- **Agree** to put **processes** in place, and to **train** applicable pharmacy staff on the JUXTAPID REMS program requirements.

The pharmacy must confirm the name of the authorized representative every year, and advise the REMS Coordinating Center promptly of any change in the AR. If the AR changes, the Pharmacy must recertify within 30 days.

To retry Question 5 click here



REMS PROGRAM

Pharmacy Training Module and Knowledge Assessment



THERE ARE **2** PAGES TO THIS FORM • ALL FIELDS ARE REQUIRED • PLEASE PRINT

JUXTAPID is only available through the JUXTAPID Risk Evaluation and Mitigation Strategy (REMS) Program.

PHARMACY

Pharmacy Name: _____ License #: _____

Address: _____

City: _____ State: _____ Zip: _____

Phone: _____ Fax: _____

AUTHORIZED PHARMACY REPRESENTATIVE

To become enrolled as a certified pharmacy under the JUXTAPID REMS Program, pharmacies must designate an authorized representative for the pharmacy. The authorized representative must complete the remainder of the form.

Name: _____ Title: _____

Email: _____

Phone: _____ Fax: _____

Authorized Pharmacy Representative Attestation

JUXTAPID is only available through the JUXTAPID REMS Program. In order to become certified and purchase, dispense and distribute JUXTAPID, pharmacies must agree to 1) recertify if there is a change in the authorized representative 2) be audited 3) provide prescription data to Amryt as requested.

As the Authorized Pharmacy Representative, I attest that:

- I have reviewed the Prescribing Information (PI) for JUXTAPID
- I have reviewed the JUXTAPID REMS Program Fact Sheet that summarizes the risks and requirements of the JUXTAPID REMS program
- I have completed the JUXTAPID REMS Program Pharmacy Training Module including the Knowledge Assessment component
- I agree to train all pharmacy staff involved with JUXTAPID in the requirement of the REMS Program.

CONTINUED ON NEXT PAGE

- I agree to put processes and procedures in place to verify, prior to dispensing JUXTAPID® (lomitapide) capsules, that:
 - The prescriber is certified in the JUXTAPID REMS Program
 - The JUXTAPID REMS Program Prescription Authorization Form is received for each new prescription
 - The JUXTAPID REMS Program Patient-Prescriber Acknowledgement Form is on file with the JUXTAPID REMS Program Coordinating Center

Signature: _____ Date: _____

This form must be completed for initial pharmacy enrollment, re-certification and after any changes with the authorized representative.

IMPORTANT

REVIEW TO ENSURE ALL FIELDS ARE COMPLETED • RETURN BOTH PAGES

Fax it to 1-855-898-2498. Or scan and email it to REMS@amrytpharma.com

If you have any questions, please contact the JUXTAPID REMS Coordinating Center.
Phone: 1-85-JUXTAPID (1-855-898-2743) | Fax: 1-855-898-2498 | www.juxtapidREMSprogram.com

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.

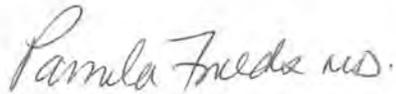
The modifications to the REMS will **require all certified pharmacies to be recertified in the JUXTAPID REMS Program by 2 July, 2017** by doing the following:

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 1-85-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