



REMS PROGRAM

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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)**



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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)**



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Pharmacy certification

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

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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](#)

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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](#)

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REMS PRO

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

CONTINUE

CANCEL

Prescriber certification

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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

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Program materials

PRESCRIBING INFORMATION

FACT SHEET

PRESCRIBER TRAINING MODULE

 PATIENT GUIDE AND
PATIENT-PRESCRIBER
ACKNOWLEDGEMENT FORM

PRESCRIBER ENROLLMENT FORM

 PRESCRIPTION
AUTHORIZATION FORM

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please call 1-85-JUXTAPID (1-855-898-2743)**



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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.