



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





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- 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:

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.





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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





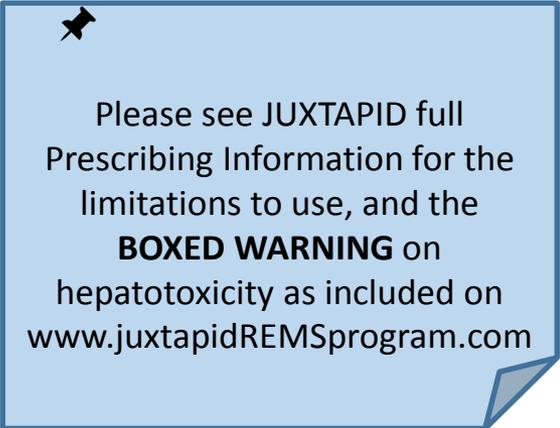
Appropriate Patient Selection

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



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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)

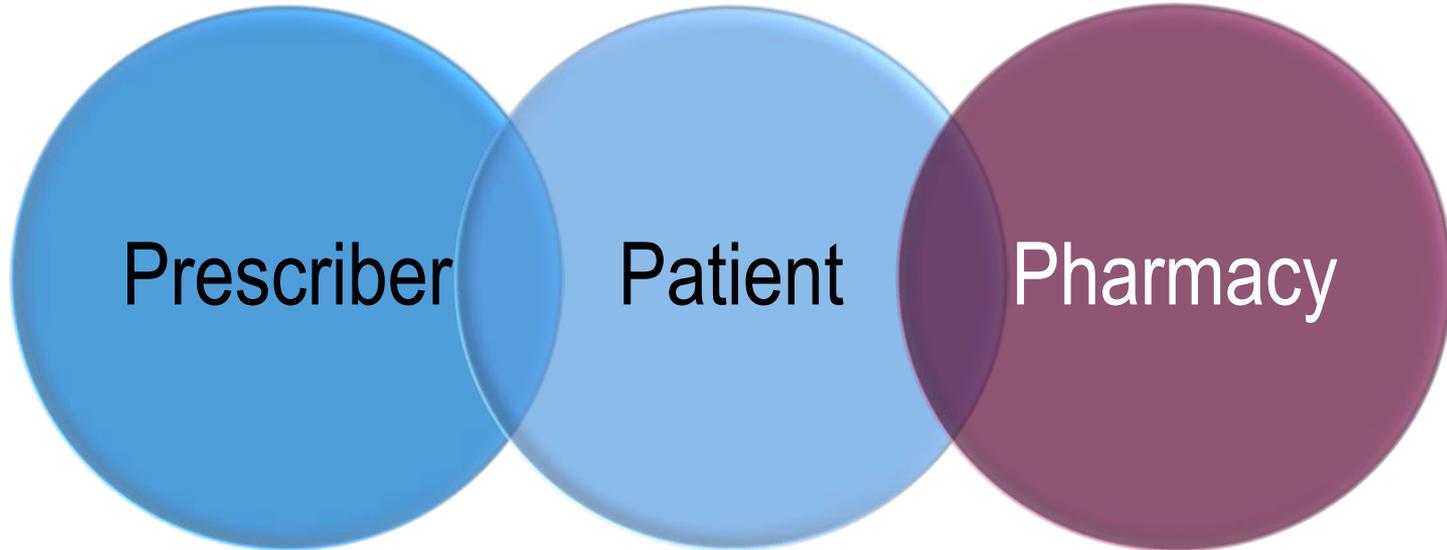
and

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



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



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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.



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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?

- a. Complete and submit the JUXTAPID REMS Program Enrollment Form.
- b. Successfully complete the JUXTAPID REMS Program Training Module and Knowledge Assessment and then submit the 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.



Question 4

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

- a. Complete and submit the JUXTAPID REMS Form.
- 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.

If "b" is selected.



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.



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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:

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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