Note to Reviewer:

The JUXTAPID REMS Pharmacy Training Module and Knowledge Assessment can be accessed online by clicking the link on the website. The participant will need to register to enter the Pharmacy Training Module and Knowledge Assessment. 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; but if this is not provided, the participant will still be able to proceed. These items will be used to generate a *Certificate of Completion* at the end of the training that is required to be submitted to enroll the pharmacy in the JUXTAPID REMS.

JUXTAPID Risk Evaluation and Mitigation Strategy (REMS)

Pharmacy Training Module and Knowledge Assessment

This interactive tool:

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

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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 and Knowledge Assessment and **print** the *Certificate of Completion* at the end of the module
- **Submit** the *Certificate of Completion* and the **signed** *Pharmacy Enrollment Form* to the JUXTAPID REMS Coordinating Center either by fax: 1-855-898-2498 or email: REMS@chiesi.com

At the end of the Pharmacy 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 *Fact Sheet* and the JUXTAPID Prescribing Information.

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

Click here to begin

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Contents

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Contents

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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)".

The purpose of this training module is to educate pharmacy representatives about the JUXTAPID REMS 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.

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JUXTAPID REMS Goals

The aim of the JUXTAPID REMS 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
- 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)

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

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Contents

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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

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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

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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) ≥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 ≥3x ULN. Discontinue JUXTAPID for clinically significant liver toxicity.

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

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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 ≥3x ULN, and 4 (14%) of the patients had at least one elevation in ALT or AST ≥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 ≥2x ULN, or active liver disease, discontinue treatment with JUXTAPID and identify the probable cause.

Continued next slide

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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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Contents

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JUXTAPID REMS Goals

The aim of the JUXTAPID REMS 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
- 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)

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

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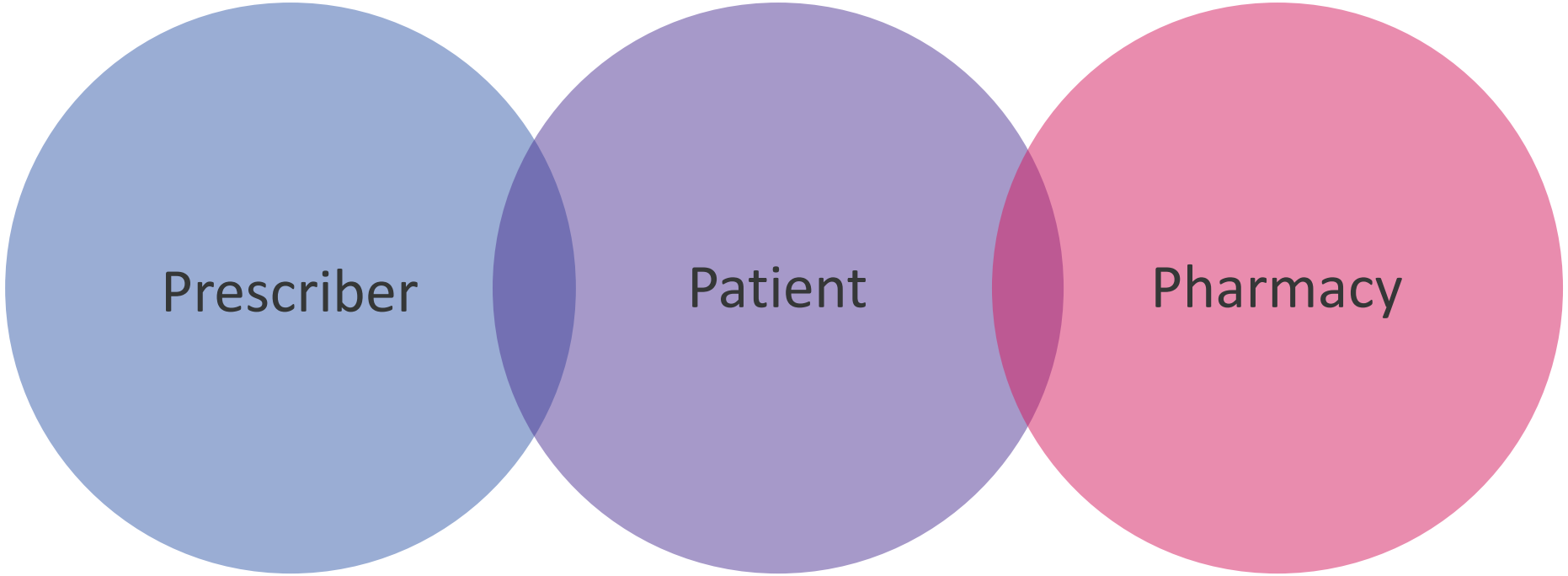
JUXTAPID REMS Key Elements



Prescribers must be certified to prescribe JUXTAPID

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

Pharmacies must be certified to distribute and dispense JUXTAPID

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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 (PPAF).* This form is attached to the *Patient Guide* and must be submitted to the JUXTAPID REMS Coordinating Center for all new patients.

The Prescriber must:

❶ **Review** the *Patient Guide* with the patient.

- This document provides a summary of JUXTAPID and the REMS requirements

❷ **Complete** the *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, understands the hepatic risk and the need for regular liver monitoring

Prescriptions will not be dispensed without a completed PPAF on record

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Pharmacy Certification Process

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Authorized Representative Requirements

For a pharmacy to be certified in the JUXTAPID REMS, 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 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.

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Pharmacy Certification Process

The Authorized Representative must:

❶ **Review** the:

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

❷ **Complete** the:

- JUXTAPID REMS Pharmacy Training Module and Knowledge Assessment

❸ **Agree** to:

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

❹ **Submit** to the REMS Coordinating Center the:

- *Certificate of Completion* for the Pharmacy Training Module and Knowledge Assessment
- Completed *Pharmacy Enrollment Form*

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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** *Patient-Prescriber Acknowledgement Form* on file for the patient.

3. The *Prescription Authorization Form* is **completed**.

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Where Do I Find the REMS Materials?

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

www.juxtapidREMSprogram.com

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

1- 855-898-2743

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Knowledge Assessment

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Question 1

The goals of the JUXTAPID REMS 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.

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Question 1

The goals of the JUXTAPID REMS 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.

Partly correct

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

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Question 1

The goals of the JUXTAPID REMS 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.

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. However, there are other goals too. Review the REMS goals and try again.

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Question 1

The goals of the JUXTAPID REMS 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.

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. However, there are other goals. Review the REMS goals and try again.

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Question 1

The goals of the JUXTAPID REMS 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.**

Correct!

All three are goals of the JUXTAPID REMS.

Click here to advance

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Question 2

Which conditions are appropriate for the use of JUXTAPID?

- ☐ Mixed dyslipidemia.
- ☐ Homozygous familial hypercholesterolemia (HoFH).
- ☐ Heterozygous familial hypercholesterolemia (HeFH).
- ☐ All of the above.

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Question 2

Which conditions are appropriate for the use of JUXTAPID?

- ☐ **Mixed dyslipidemia.**
- ☐ Homozygous familial hypercholesterolemia (HoFH).
- ☐ Heterozygous familial hypercholesterolemia (HeFH).
- ☐ 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.

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Question 2

Which conditions are appropriate for the use of JUXTAPID?

- ☐ Mixed dyslipidemia.
- ☐ **Homozygous familial hypercholesterolemia (HoFH).**
- ☐ Heterozygous familial hypercholesterolemia (HeFH).
- ☐ 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

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Question 2

Which conditions are appropriate for the use of JUXTAPID?

- ☐ Mixed dyslipidemia.
- ☐ Homozygous familial hypercholesterolemia (HoFH).
- ☐ **Heterozygous familial hypercholesterolemia (HeFH).**
- ☐ 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.

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Question 2

Which conditions are appropriate for the use of JUXTAPID?

- ☐ Mixed dyslipidemia.
- ☐ Homozygous familial hypercholesterolemia (HoFH).
- ☐ Heterozygous familial hypercholesterolemia (HeFH).
- ☐ **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.

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Question 3

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

- ☐ True
- ☐ False

Question 3

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

- ☐ **True**
- ☐ False

Correct!

JUXTAPID is associated with a risk of hepatotoxicity and as a result there is a REMS in place to ensure that its benefits outweigh its risks. The REMS 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

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Question 3

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

- ☐ True
- ☐ **False**

Incorrect

Review the goals of the JUXTAPID REMS and retry this question.

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Question 4

How does a pharmacy become certified in the JUXTAPID REMS?

- ☐ Complete and submit the *Pharmacy Enrollment Form*.
- ☐ Successfully complete the Pharmacy Training Module and Knowledge Assessment and then submit the *Certificate of Completion*.
- ☐ Review the JUXTAPID PI and the *Fact Sheet*.
- ☐ Assign an authorized representative.
- ☐ All of the above.

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Question 4

How does a pharmacy become certified in the JUXTAPID REMS?

- ☐ **Complete and submit the *Pharmacy Enrollment Form*.**
- ☐ Successfully complete the Pharmacy Training Module and Knowledge Assessment and then submit the *Certificate of Completion*.
- ☐ Review the JUXTAPID PI and the *Fact Sheet*.
- ☐ Assign an authorized representative.
- ☐ All of the above.

Partly Correct

To become a certified pharmacy in the JUXTAPID REMS 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 *Fact Sheet*. 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.

Review the Pharmacy Certification Process and try again.

Question 4

How does a pharmacy become certified in the JUXTAPID REMS?

- ☐ Complete and submit the *Pharmacy Enrollment Form*.
- ☐ **Successfully complete the Pharmacy Training Module and Knowledge Assessment and then submit the *Certificate of Completion*.**
- ☐ Review the JUXTAPID PI and the *Fact Sheet*.
- ☐ Assign an authorized representative.
- ☐ All of the above.

Partly Correct

To become a certified pharmacy in the JUXTAPID REMS 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 *Fact Sheet*. 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.

Review the Pharmacy Certification Process and try again.

Question 4

How does a pharmacy become certified in the JUXTAPID REMS?

- ☐ Complete and submit the *Pharmacy Enrollment Form*.
- ☐ Successfully complete the Pharmacy Training Module and Knowledge Assessment and then submit the *Certificate of Completion*.
- ☐ **Review the JUXTAPID PI and the *Fact Sheet*.**
- ☐ Assign an authorized representative.
- ☐ All of the above.

Partly Correct

To become a certified pharmacy in the JUXTAPID REMS 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 *Fact Sheet*. 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.

Review the Pharmacy Certification Process and try again.

Question 4

How does a pharmacy become certified in the JUXTAPID REMS?

- ☐ Complete and submit the *Pharmacy Enrollment Form*.
- ☐ Successfully complete the Pharmacy Training Module and Knowledge Assessment and then submit the *Certificate of Completion*.
- ☐ Review the JUXTAPID PI and the *Fact Sheet*.
- ☐ **Assign an authorized representative.**
- ☐ All of the above.

Partly Correct

To become a certified pharmacy in the JUXTAPID REMS 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 *Fact Sheet*. 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.

Review the Pharmacy Certification Process and try again.

Question 4

How does a pharmacy become certified in the JUXTAPID REMS?

- ☐ Complete and submit the *Pharmacy Enrollment Form*.
- ☐ Successfully complete the Pharmacy Training Module and Knowledge Assessment and then submit the *Certificate of Completion*.
- ☐ Review the JUXTAPID PI and the *Fact Sheet*.
- ☐ Assign an authorized representative.
- ☐ **All of the above.**

Correct!

To become a certified pharmacy in the JUXTAPID REMS 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 *Fact Sheet*. 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.

Click here to advance

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Question 5

What is <u>not</u> a requirement of the Authorized Pharmacy Representative?

- ☐ Review the *Fact Sheet*.
- ☐ Oversee the conduct of the JUXTAPID REMS at the pharmacy.
- ☐ Complete the *Patient-Prescriber Acknowledgement Form.*
- ☐ Put processes and procedures in place to ensure the JUXTAPID REMS requirements are met.

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Question 5

What is not a requirement of the Authorized Pharmacy Representative?

- ☐ **Review the *Fact Sheet*.**
- ☐ Oversee the conduct of the JUXTAPID REMS at the pharmacy.
- ☐ Complete the *Patient-Prescriber Acknowledgement Form.*
- ☐ Put processes and procedures in place to ensure the JUXTAPID REMS requirements are met.

Incorrect

The Authorized Representative of the pharmacy is required to review the *Fact Sheet* 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.

Question 5

What is not a requirement of the Authorized Pharmacy Representative?

- ☐ Review the *Fact Sheet*.
- ☐ **Oversee the conduct of the JUXTAPID REMS at the pharmacy.**
- ☐ Complete the *Patient-Prescriber Acknowledgement Form.*
- ☐ Put processes and procedures in place to ensure the JUXTAPID REMS requirements are met.

Incorrect

The Authorized Representative of the pharmacy is required to review the *Fact Sheet* 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.

Question 5

What is <u>not</u> a requirement of the Authorized Pharmacy Representative?

- ☐ Review the *Fact Sheet*.
- ☐ Oversee the conduct of the JUXTAPID REMS at the Pharmacy.
- ☐ **Complete the *Patient-Prescriber Acknowledgement Form.***
- ☐ Put processes and procedures in place to ensure the JUXTAPID REMS requirements are met.

Correct!

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

Click here to advance

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Question 5

What is not a requirement of the Authorized Pharmacy Representative?

- ☐ Review the *Fact Sheet*.
- ☐ Oversee the conduct of the JUXTAPID REMS at the pharmacy.
- ☐ Complete the *Patient-Prescriber Acknowledgement Form.*
- ☐ **Put processes and procedures in place to ensure the JUXTAPID REMS requirements are met.**

Incorrect

The Authorized Representative of the Pharmacy is required to review the *Fact Sheet* 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 Training Module and Knowledge Assessment.

To finalize your certification, complete the following next steps:

- **Obtain** the *Certificate of Completion* for the Pharmacy Training Module and Knowledge Assessment

  Click here for a copy of your *Certificate of Completion*

- **Complete and sign** the *Pharmacy Enrollment Form*
- **Submit both** documents to the JUXTAPID REMS Coordinating Center either by fax: 1-855-898-2498 or email: REMS@chiesi.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.

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Note to Reviewer:

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

JUXTAPID REMS Goals

The aim of the JUXTAPID REMS 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
- 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)

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

To retry Question 1 click here

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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

To retry Question 2 click here

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JUXTAPID REMS Goals

The aim of the JUXTAPID REMS 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
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❷ JUXTAPID is **dispensed only to patients with a clinical or laboratory diagnosis consistent with homozygous familial hypercholesterolemia** (HoFH)

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

To retry Question 3 click here

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Pharmacy Certification Process

The Authorized Representative must:

❶ **Review** the:

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

❷ **Complete** the:

- Pharmacy Training Module and Knowledge Assessment

❸ **Agree** to:

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

❹ **Submit** to the REMS Coordinating Center the:

- *Certificate of Completion* for the Pharmacy Training Module and Knowledge Assessment
- Completed *Pharmacy Enrollment Form*

To retry Question 4 click here

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Authorized Representative Requirements

For a pharmacy to be certified in the JUXTAPID REMS, 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 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.

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