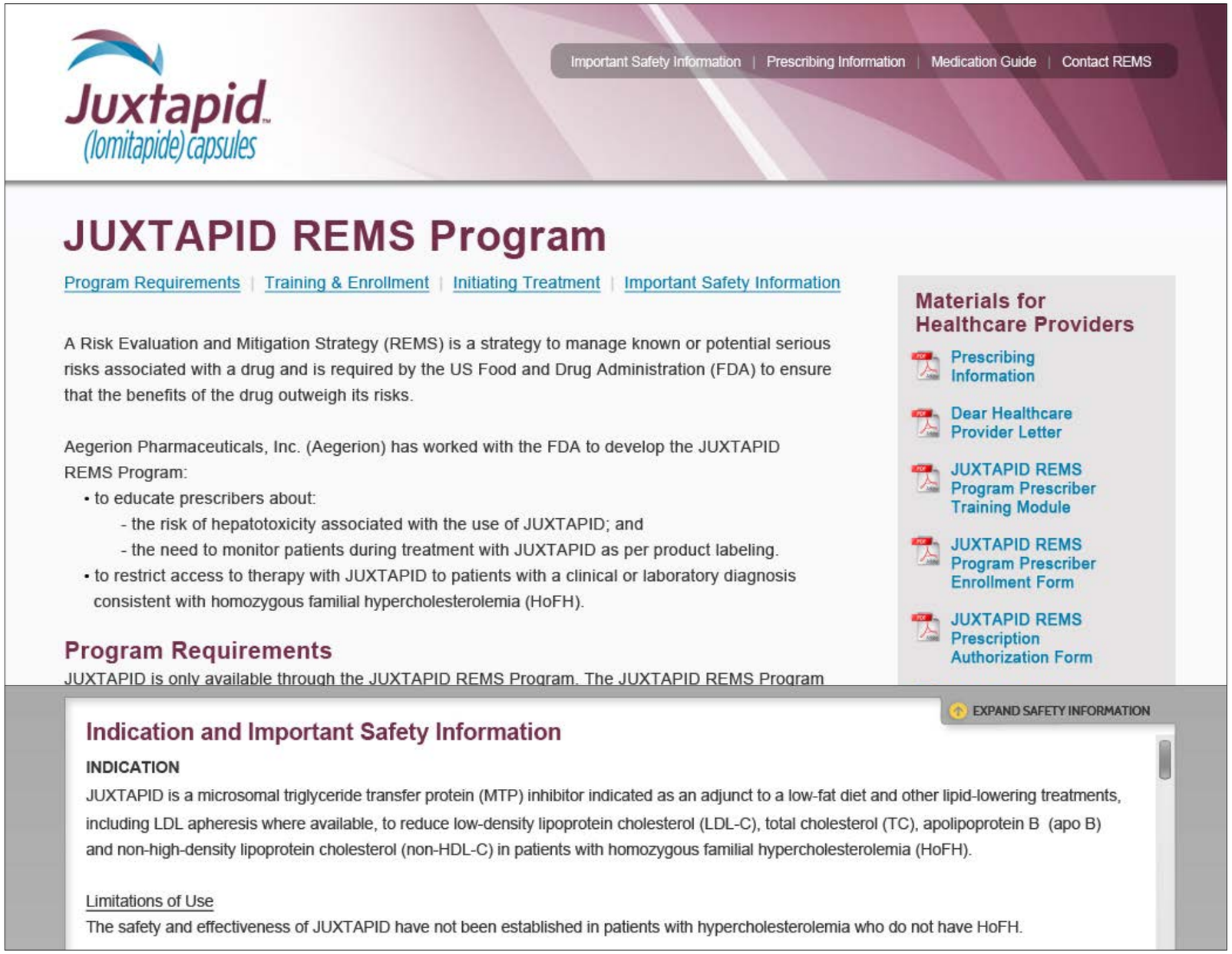

STICKY ISI FOOTER
This element will be "sticky" on bottom of the browser. The user can scroll through the content or click here to expand to get a larger view of the ISI.

Functionality examples available here:
www.tracleer.com
www.pradaxapro.com

requirements include:

Contact REMS

- For Prescribers
  - **Training** on the risk of hepatotoxicity associated with the use of JUXTAPID; appropriate patient selection and monitoring; and the REMS requirements
  - **Certification** by completion of training, and enrollment in the JUXTAPID REMS Program
  - **Attestation** of patient safe use for each new prescription by completing a Prescription Authorization Form

Find out more about Training and Enrollment

- For Pharmacies
  - Certification and enrollment in the REMS Program in order to dispense JUXTAPID
  - **Restricted distribution** of JUXTAPID to patients with prescriptions from prescribers who are enrolled in the JUXTAPID REMS Program
  - Prescriber documentation of safe use conditions with Presciption Authorization Form

Training & Enrollment

Healthcare professionals who prescribe JUXTAPID must review the prescriber training materials to enroll in the JUXTAPID REMS Program.

Steps to Prescriber Certification

1 **Review the Prescriber Education Materials**

- JUXTAPID Prescribing Information

EXPAND SAFETY INFORMATION

Indication and Important Safety Information

INDICATION

JUXTAPID is a microsomal triglyceride transfer protein (MTP) inhibitor 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.

REVIEW

- Prescriber Training Module

2

COMPLETE and SUBMIT

Complete and Submit the JUXTAPID REMS Program Prescriber Enrollment Form

- Print and sign the Prescriber Enrollment Form or request a copy by calling: 1-85-JUXTAPID (1-855-898-2743)
- Submit the form via:
  - Fax to 1-855-898-2498
  - Scan form and e-mail to REMS@aegerion.com

By completing the Prescriber Enrollment Form, the prescriber agrees to comply with the JUXTAPID REMS Program requirements. A confirmation of your certification in the JUXTAPID REMS Program will be sent to you so you can begin to prescribe JUXTAPID.

Initiating Treatment

Before starting a patient on JUXTAPID, enrolled prescribers must:

- Affirm that the patient has a clinical or laboratory diagnosis consistent with HoFH.
- Obtain liver-related laboratory tests as directed in the JUXTAPID prescribing information.
- Confirm the absence of pregnancy and counsel the patient about the potential for fetal harm, if the patient is a woman of reproductive potential. Instruct her to use reliable methods of contraception and confirm use. Instruct patients to contact their prescriber immediately and stop taking JUXTAPID if pregnancy should occur.
- Complete and submit the prescription using the JUXTAPID REMS Prescription Authorization Form documenting safe use conditions. A Prescription Authorization Form is required to be submitted for each new prescription.

EXPAND SAFETY INFORMATION

Indication and Important Safety Information

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Limitations of Use

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JUXTAPID REMS Program – Contact Us

Phone: 1-85-JUXTAPID (1-855-898-2743)
Fax: 1-855-898-2498
E-mail: REMS@aegerion.com
Hours of Operation: Monday-Friday: 8 AM-7 PM ET

To learn more about the risk of hepatotoxicity associated with the use of JUXTAPID, please refer to the Prescribing Information. Before initiating treatment with JUXTAPID, prescribers must discuss the risks of JUXTAPID with their patients.

Reporting of Adverse Reactions

All healthcare professionals should report all suspected adverse reactions. Please contact Aegerion Pharmaceuticals, Inc. at 1-855-303-2347 or the FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

This site is intended for U.S. residents only.

Aegerion® Pharmaceuticals

EXPAND SAFETY INFORMATION

Indication and Important Safety Information

INDICATION

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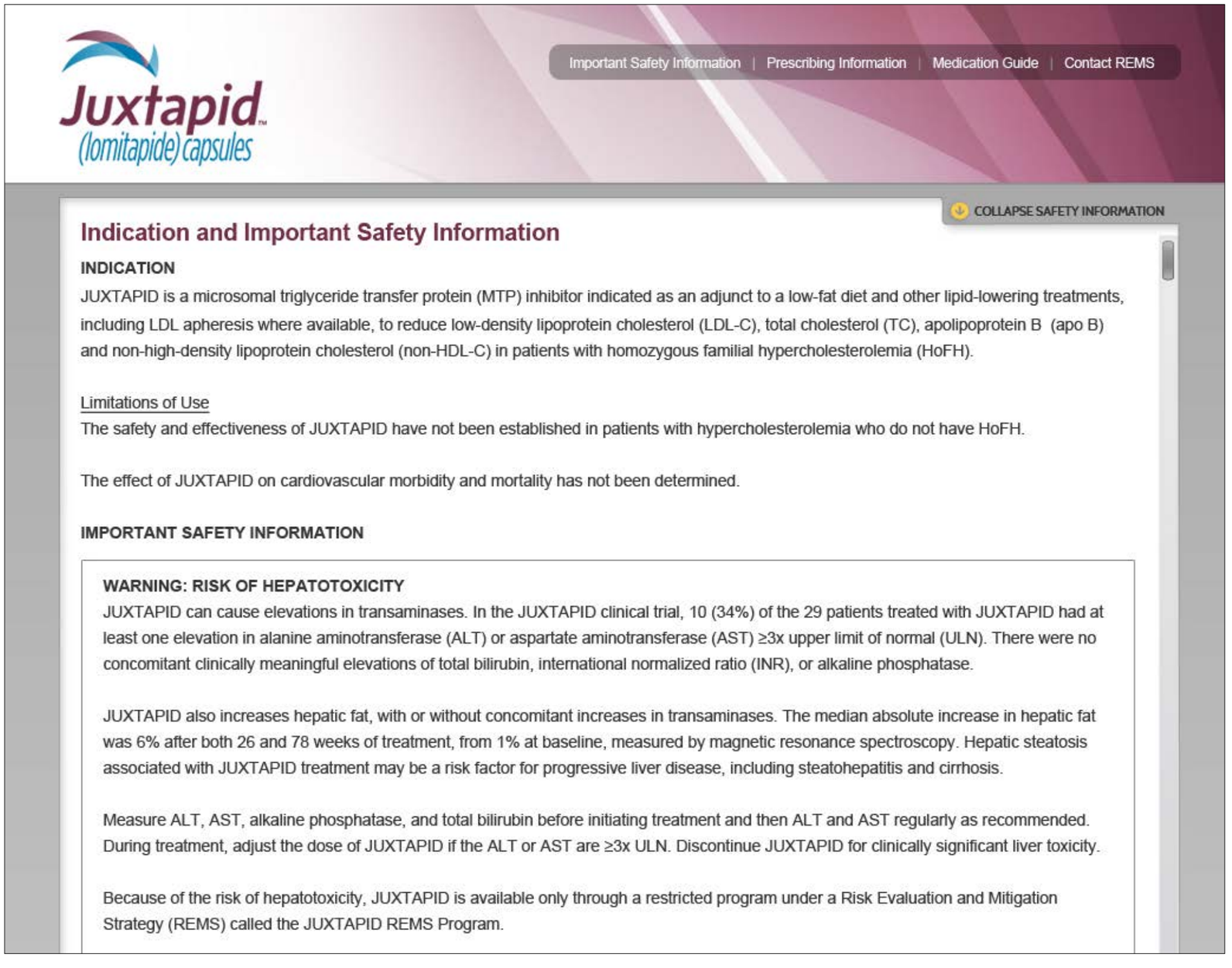
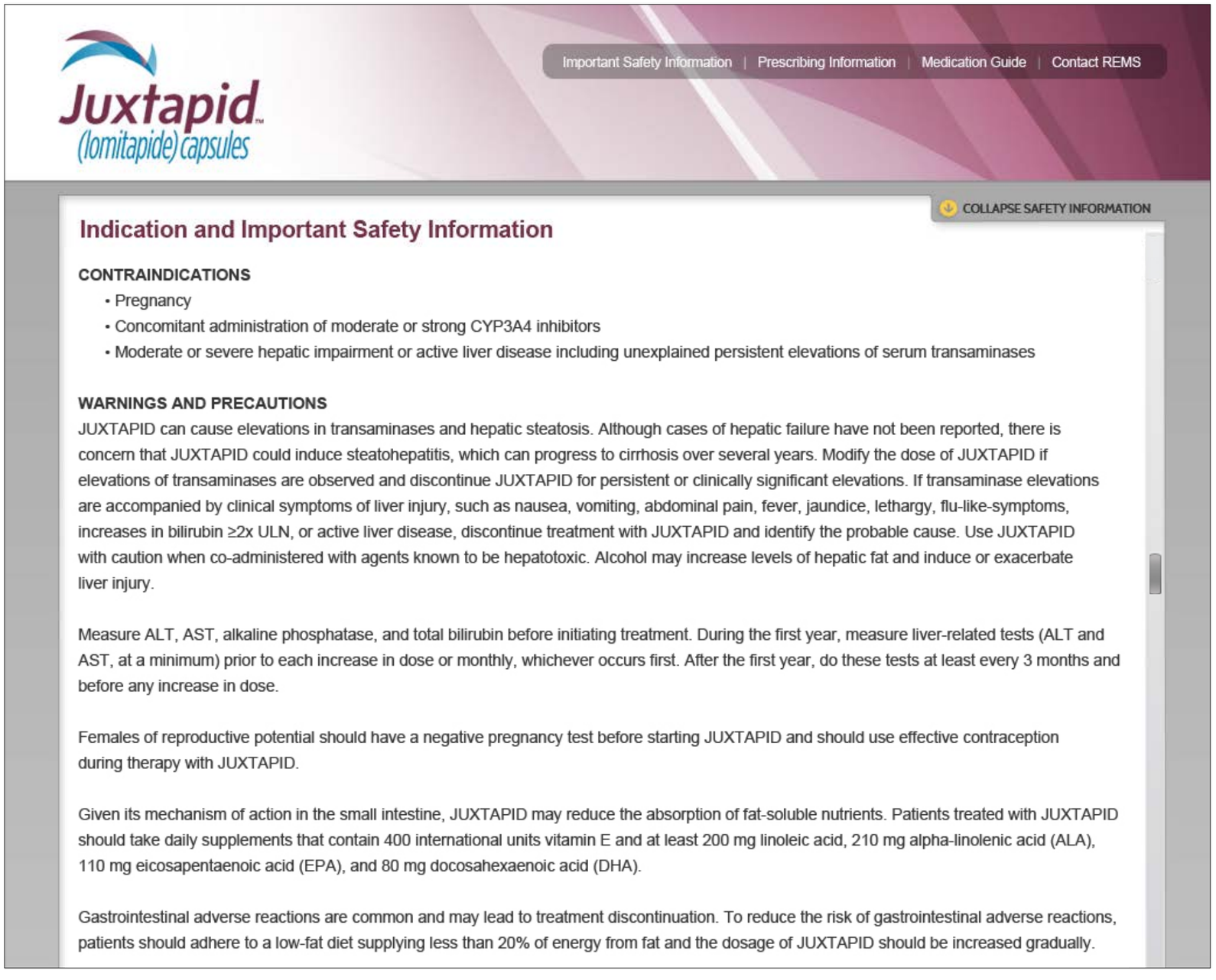
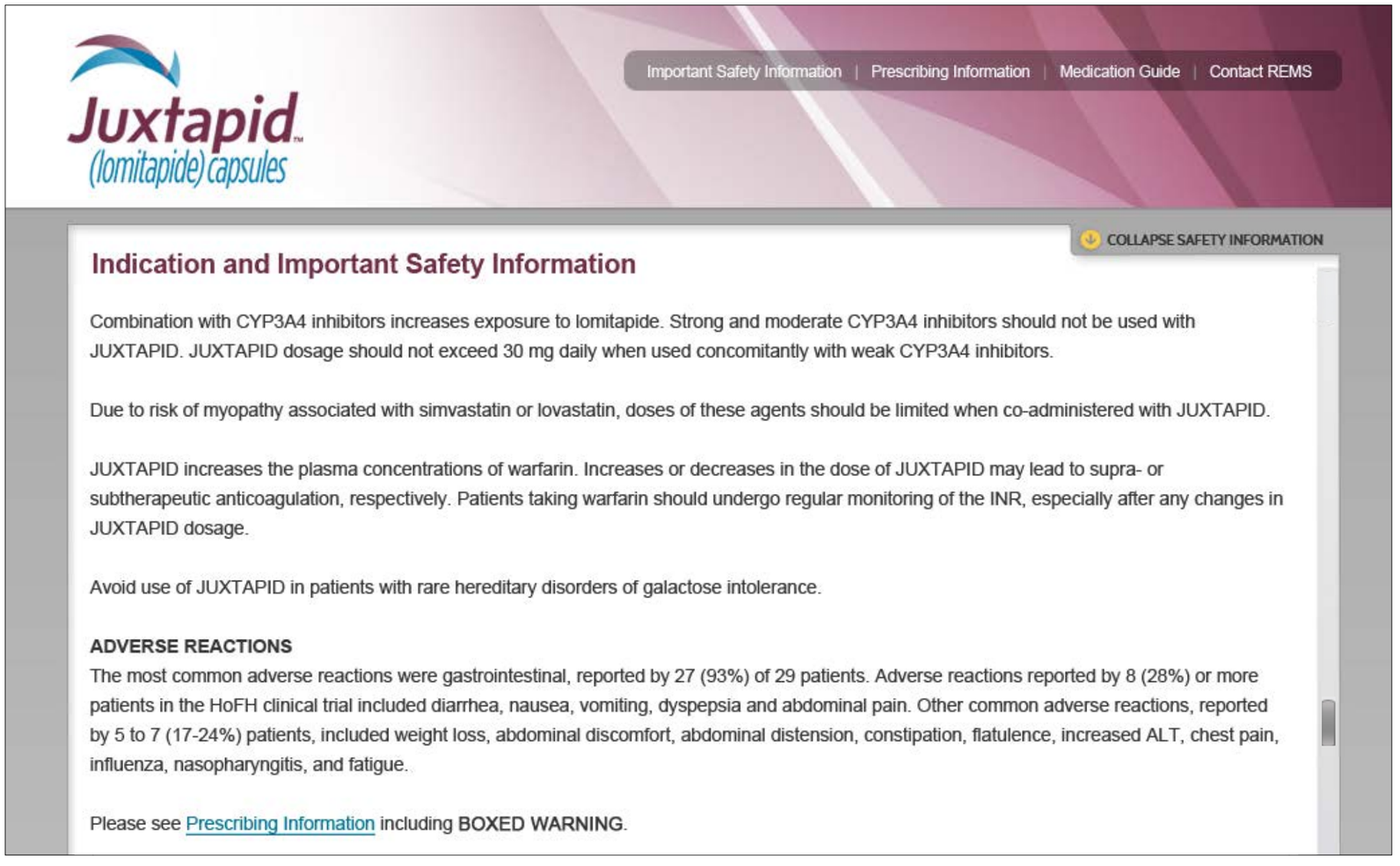

Juxtapid
(lomitapide) capsules
Important Safety Information | Prescribing Information | Medication Guide | Contact REMS
COLLAPSE SAFETY INFORMATION
Indication and Important Safety Information
INDICATION
JUXTAPID is a microsomal triglyceride transfer protein (MTP) inhibitor indicated as an adjunct to 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.
The effect of JUXTAPID on cardiovascular morbidity and mortality has not been determined.
IMPORTANT SAFETY INFORMATION
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% at 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 the dose of JUXTAPID if the ALT or AST are ≥3x ULN. Discontinue JUXTAPID for clinically significant liver toxicity.
Because of the risk of hepatotoxicity, JUXTAPID is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called the JUXTAPID REMS Program.


Juxtapid
(lomitapide) capsules
Important Safety Information | Prescribing Information | Medication Guide | Contact REMS
COLLAPSE SAFETY INFORMATION
Indication and Important Safety Information
CONTRAINDICATIONS
• Pregnancy
• Concomitant administration of moderate or strong CYP3A4 inhibitors
• Moderate or severe hepatic impairment or active liver disease including unexplained persistent elevations of serum transaminases
WARNINGS AND PRECAUTIONS
JUXTAPID can cause elevations in transaminases and hepatic steatosis. 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. Modify the dose of JUXTAPID if elevations of transaminases are observed and 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 ≥2x ULN, or active liver disease, discontinue treatment with JUXTAPID and identify the probable cause. Use JUXTAPID with caution when co-administered with agents known to be hepatotoxic. Alcohol may increase levels of hepatic fat and induce or exacerbate liver injury.
Measure ALT, AST, alkaline phosphatase, and total bilirubin before initiating treatment. During the first year, measure liver-related tests (ALT and AST, at a minimum) prior to each increase in dose or monthly, whichever occurs first. After the first year, do these tests at least every 3 months and before any increase in dose.
Females of reproductive potential should have a negative pregnancy test before starting JUXTAPID and should use effective contraception during therapy with JUXTAPID.
Given its mechanism of action in the small intestine, JUXTAPID may reduce the absorption of fat-soluble nutrients. Patients treated with JUXTAPID should take daily supplements that contain 400 international units vitamin E and at least 200 mg linoleic acid, 210 mg alpha-linolenic acid (ALA), 110 mg eicosapentaenoic acid (EPA), and 80 mg docosahexaenoic acid (DHA).
Gastrointestinal adverse reactions are common and may lead to treatment discontinuation. To reduce the risk of gastrointestinal adverse reactions, patients should adhere to a low-fat diet supplying less than 20% of energy from fat and the dosage of JUXTAPID should be increased gradually.


Juxtapid
(lomitapide) capsules
Important Safety Information | Prescribing Information | Medication Guide | Contact REMS
COLLAPSE SAFETY INFORMATION
Indication and Important Safety Information
Combination with CYP3A4 inhibitors increases exposure to lomitapide. Strong and moderate CYP3A4 inhibitors should not be used with JUXTAPID. JUXTAPID dosage should not exceed 30 mg daily when used concomitantly with weak CYP3A4 inhibitors.
Due to risk of myopathy associated with simvastatin or lovastatin, doses of these agents should be limited when co-administered with JUXTAPID.
JUXTAPID increases the plasma concentrations of warfarin. Increases or decreases in the dose of JUXTAPID may lead to supra- or subtherapeutic anticoagulation, respectively. Patients taking warfarin should undergo regular monitoring of the INR, especially after any changes in JUXTAPID dosage.
Avoid use of JUXTAPID in patients with rare hereditary disorders of galactose intolerance.
ADVERSE REACTIONS
The most common adverse reactions were gastrointestinal, reported by 27 (93%) of 29 patients. Adverse reactions reported by 8 (28%) or more patients in the HoFH clinical trial included diarrhea, nausea, vomiting, dyspepsia and abdominal pain. Other common adverse reactions, reported by 5 to 7 (17-24%) patients, included weight loss, abdominal discomfort, abdominal distension, constipation, flatulence, increased ALT, chest pain, influenza, nasopharyngitis, and fatigue.
Please see Prescribing Information including BOXED WARNING.