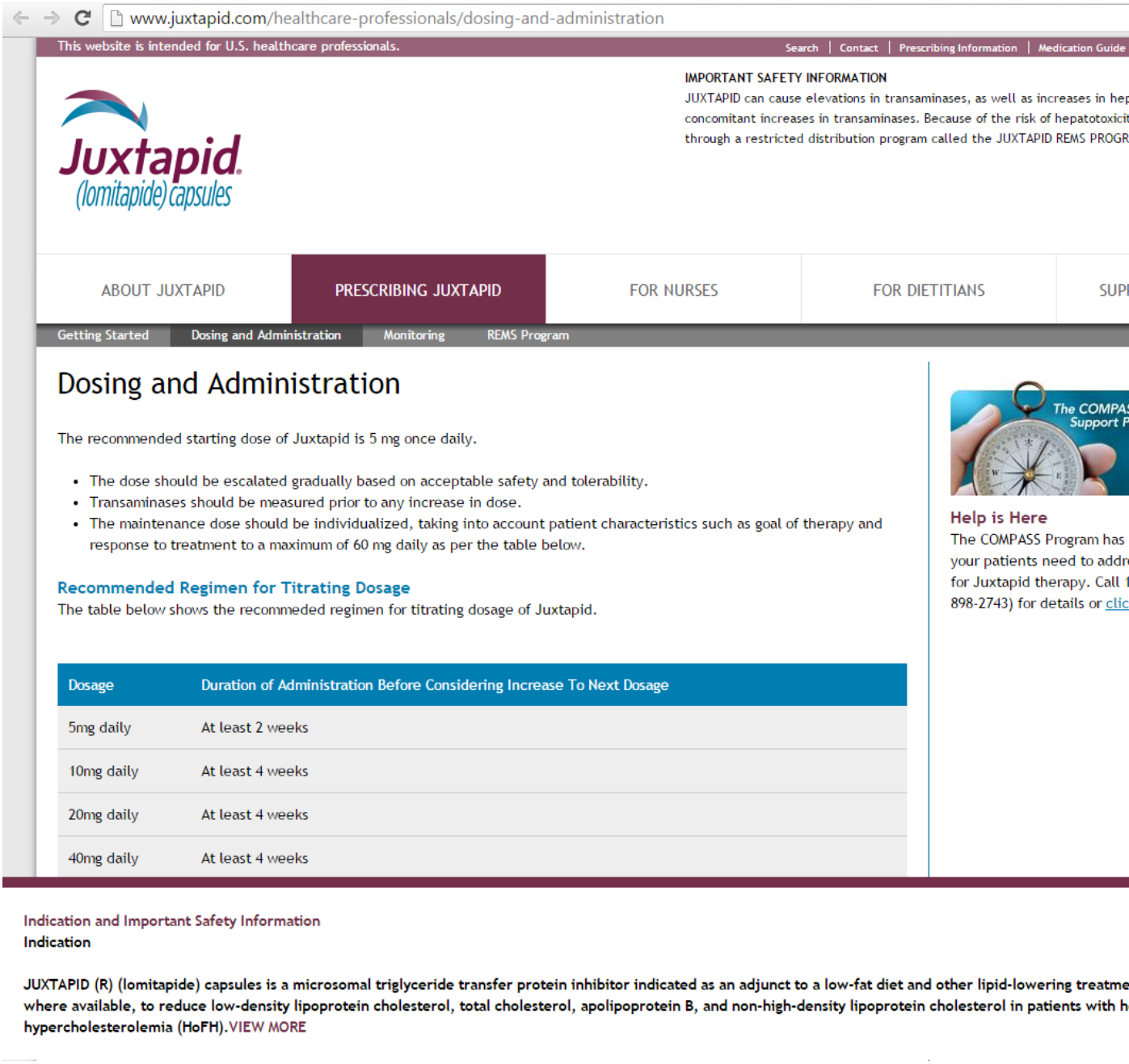

www.juxtapid.com/healthcare-professionals/dosing-and-administration

40mg daily	At least 4 weeks
60mg daily	Maximum recomended dosage

Administration

Juxtapid should be taken in the evening, with a glass of water, without food, and at least 2 hours after dinner. Administration with food may increase the risk of gastrointestinal adverse reactions. Patients should swallow Juxtapid capsules whole.

Administration of Juxtapid and bile acid sequestrants should be separated by at least 4 hours since bile acid sequestrants can interfere with the absorption of oral medications.

Because of Juxtapid's mechanism of action in the small intestine, fat-soluble vitamins/fatty acids may not be properly absorbed. Patients on Juxtapid should take daily supplements containing 400 IU vitamin E and at least 200 mg linoleic acid, 210 mg alpha-linoleic acid (ALA), 110 mg eicosapentaenoic acid (EPA), and 80 mg docosahexaenoic acid (DHA).

Dosing Adjustments

Dosing modifications are recommended for patients taking concomitant CYP3A4 inhibitors, renal impairment, or baseline hepatic impairment. Dosing adjustments are also required for patients who develop transaminases values ≥3x the upper limit of normal (ULN) during treatment with Juxtapid. Learn more here. Click the tabs below for recommended dosing modifications.

- Dosing with Cytochrome P450 3A4 Inhibitors
- Dosing in Patients with Renal Impairment
- Dosing in Patients with Baseline Hepatic Impairment
- Dose Modifications Based on Elevated Transaminases

INDICATION AND IMPORTANT SAFETY INFORMATION

Indication

JUXTAPID (R) (lomitapide) capsules is a microsomal triglyceride transfer protein inhibitor indicated as an adjunct to a low-fat diet and other lipid-lowering treat apheresis where available, to reduce low-density lipoprotein cholesterol, total cholesterol, apolipoprotein B, and non-high-density lipoprotein cholesterol in pa 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, includin familial hypercholesterolemia (HeFH). The effect of JUXTAPID on cardiovascular morbidity and mortality has not been determined.

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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 aminotransferase (ALT) or aspartate aminotransferase (AST) ≥3x upper limit of normal (ULN). There were no concomitant clinically meaningful elevations o 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 treatment, from 1% at baseline, measured by magnetic resonance spectroscopy. Hepatic steatosis associated with JUXTAPID treatment may be a risk factor 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, 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 Program.

Prescribe JUXTAPID only to patients with a clinical or laboratory diagnosis consistent with HoFH. The safety and effectiveness of JUXTAPID have not been es with hypercholesterolemia who do not have HoFH.

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 steatohepatitis, which can progress to cirrhosis over several years. Modify the dose of JUXTAPID if elevations of transaminases are observed and discontinue JUX clinically significant elevations. If transaminase elevations are accompanied by clinical symptoms of liver injury, such as nausea, vomiting, abdominal pain, fever flu-like-symptoms, increases in bilirubin ≥2x ULN, or active liver disease, discontinue treatment with JUXTAPID and identify the probable cause. Use JUXTAPID w 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 mini 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.

JUXTAPID may cause fetal harm when administered to a pregnant woman. Females of reproductive potential should have a negative pregnancy test before startin use effective contraception during therapy with JUXTAPID. The recommended maximum dosage of JUXTAPID is 40 mg daily when used concomitantly with oral co

Given its mechanism of action in the small intestine, JUXTAPID may reduce the absorption of fat-soluble nutrients. Patients treated with JUXTAPID should take d

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Gastrointestinal adverse reactions are common and may lead to treatment discontinuation. Instruct patients to stop JUXTAPID and contact their healthcare provid occurs, or if they experience symptoms of volume depletion such as lightheadedness, decreased urine output, or tiredness. In such cases, consider reducing the of JUXTAPID. 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 should be increased gradually.

Weak CYP3A4 inhibitors can increase the exposure of lomitapide approximately 2-fold; therefore, when JUXTAPID is administered with weak CYP3A4 inhibitors, t should be decreased by half and the recommended maximum dosage of JUXTAPID is 30 mg daily. The recommended maximum dosage is 40 mg daily when used c contraceptives. Strong and moderate CYP3A4 inhibitors should not be used with Juxtapid. Patients taking JUXTAPID 5 mg daily may continue with the same dosag

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, 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 diseases 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 HoF diarrhea, nausea, vomiting, dyspepsia and abdominal pain. Other common adverse reactions, reported by 5 to 7 (17-24%) patients, included weight loss, abdomin distension, constipation, flatulence, increased ALT, chest pain, influenza, nasopharyngitis, and fatigue.

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-F http://www.fda.gov/medwatch.

Please see Prescribing Information including BOXED WARNING.