

Medication Guide

JUXTAPID® (JUKS-tuh-pid)

(lomitapide)
capsules

What is the most important information I should know about JUXTAPID?

- JUXTAPID is available only through certified pharmacies that are enrolled in the JUXTAPID REMS Program. Your doctor must be enrolled in the program in order for you to be prescribed JUXTAPID.
- There is a registry that collects information about the effects of taking JUXTAPID over time. Ask your doctor for more information about this registry or visit www.JUXTAPID.com or call 1-877-902-4099.

JUXTAPID may cause serious side effects including:

- 1. Liver problems.** JUXTAPID can cause liver problems such as increased liver enzymes or increased fat in the liver.
 - Your doctor should do blood tests to check your liver before you start JUXTAPID, if your dose is increased, and while you take JUXTAPID. If your tests show some liver problems, your doctor may adjust your dose of JUXTAPID or stop it altogether.
 - Tell your doctor if you have had liver problems, including liver problems while taking other medicines.
 - JUXTAPID may cause nausea, vomiting and stomach pain, especially if you do not eat a low-fat diet. These side effects can also be symptoms of liver problems.
 - Tell your doctor right away if you have any of these symptoms of liver problems while taking JUXTAPID:
 - Nausea, vomiting, or stomach pain that gets worse, does not go away, or changes
 - fever
 - flu-like symptoms
 - yellowing of your eyes or skin
 - you are more tired than usual
 - Drinking alcohol may increase your chance of having liver problems or make your liver problems worse. You should not have more than 1 alcoholic drink each day while taking JUXTAPID.
- 2. Harm to your unborn baby.** JUXTAPID may cause harm to your unborn baby.
 - If you are pregnant, think you may be pregnant, or are planning to become pregnant, **do not** take JUXTAPID.
 - If you are a female who can get pregnant, you should have a pregnancy test before you start taking JUXTAPID. Your pregnancy test must be negative for you to get JUXTAPID.
 - **Do not** have sex while taking JUXTAPID unless you are using effective birth control.
 - Talk with your doctor or nurse to find the best method of birth control for you.
 - Birth control pills may not work as well if you have diarrhea or vomiting.
 - If you start taking birth control pills while you are taking JUXTAPID, tell your doctor. Your doctor might need to change your dose of JUXTAPID.
 - If you become pregnant while taking JUXTAPID, stop taking JUXTAPID and call your doctor right away.
 - Pregnancy Exposure Registry: There is a pregnancy exposure registry that monitors outcomes in women exposed to JUXTAPID during pregnancy. If you become pregnant while taking JUXTAPID, call 1-877-902-4099 or visit www.JUXTAPID.com for more information about the JUXTAPID pregnancy exposure registry.

What is JUXTAPID?

JUXTAPID is a prescription medicine used along with diet and other lipid-lowering treatments, including low-density lipoprotein (LDL) apheresis where available, in people with homozygous familial hypercholesterolemia (HoFH) to reduce:

- LDL ("bad") cholesterol
- total cholesterol
- a protein that carries "bad" cholesterol in the blood (apolipoprotein B)
- non-high-density lipoprotein cholesterol (non-HDL-C)

It is not known if JUXTAPID can decrease problems from high cholesterol, such as heart attack, stroke, death or other health problems.

It is not known if JUXTAPID is safe and effective in people with high cholesterol who do not have HoFH, including those with heterozygous familial hypercholesterolemia (HeFH).

JUXTAPID should not be taken with certain medicines or food. You should not drink grapefruit juice. Ask your doctor or pharmacist to make sure you can take JUXTAPID with your other medicines, and tell your doctor about any new medicines you might take even for only a short time.

It is not known if JUXTAPID is safe and effective in people with kidney problems including people with end-stage kidney disease who are not on dialysis.

It is not known if JUXTAPID is safe and effective when used in children under the age of 18.

Who should not take JUXTAPID?**Do not take JUXTAPID if you:**

- are pregnant, think you may be pregnant, or are planning to become pregnant. See **“What is the most important information I should know about JUXTAPID?”**
- take medicines that affect how the body breaks down JUXTAPID (that is, strong or moderate CYP3A4 inhibitors). Check with your doctor and/or pharmacist to see if you are taking any of these medications. These may include certain medications intended to treat bacterial, fungal or viral infections, and medications to treat depression, high blood pressure, or angina.
- drink grapefruit juice.
- have moderate or severe liver problems or active liver disease, including people who have unexplained abnormal liver tests.

What should I tell my doctor before taking JUXTAPID?**Before you take JUXTAPID, tell your doctor if you:**

- have liver problems
- have kidney problems
- have intestine or bowel problems
- drink alcohol
- are breastfeeding or plan to breastfeed. It is not known if JUXTAPID passes into your breast milk. You and your doctor should decide if you will take JUXTAPID or breastfeed. You should not do both.

Tell your doctor about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

Before starting a new medicine while taking JUXTAPID, even if you will only be taking it for a short time, ask your doctor or pharmacist if it is safe to take with JUXTAPID.

JUXTAPID may affect the way other medicines work, and other medicines may affect how JUXTAPID works.

Certain medicines can affect how your liver breaks down other medicines.

Especially tell your doctor if you take:

- a blood thinner called warfarin
- medicines for high cholesterol, including statins such as atorvastatin or simvastatin, and resins such as colestevlam or cholestyramine
- medicines for bacteria, fungus, or viral infection (including HIV and hepatitis C)
- medicines for depression, high blood pressure, or angina
- birth control pills

Know the medicines you take. Keep a list of them to show your doctor and pharmacist when you get a new medicine.

How should I take JUXTAPID?

- Take JUXTAPID exactly as your doctor tells you to take it.
- Your doctor will tell you how much JUXTAPID to take and when to take it.
- Your doctor may change your dose of JUXTAPID if needed.
- Do not change your JUXTAPID dose yourself.
- Take JUXTAPID 1 time each day at least 2 hours after your evening meal.
- Take JUXTAPID with water.
- You should not take JUXTAPID with food. Taking JUXTAPID with food may cause stomach problems.
- Take JUXTAPID capsules whole. Do not open, crush, dissolve, or chew capsules before swallowing. If you cannot swallow JUXTAPID capsules whole, tell your doctor. You may need a different medicine.
- If you take a medicine that lowers cholesterol by binding bile acids, such as colestevlam or cholestyramine, take it at least 4 hours before or 4 hours after you take JUXTAPID. Ask your doctor if you are not sure if you take these medicines.
- To help lower the chance of stomach problems, stay on a low-fat diet. Ask your doctor about talking to a dietician to learn what you should eat while taking JUXTAPID. JUXTAPID makes it harder for some nutrients to get into your body. Take Vitamin E and fatty acids each day while you take JUXTAPID. Ask your doctor, nurse, or dietician how to add them to your diet.
- If you take too much JUXTAPID, call your doctor right away.
- Do not stop JUXTAPID unless your doctor tells you to stop it.
- If you miss a dose of JUXTAPID, take your usual dose the next day at the usual time. If you stop taking JUXTAPID for more than a week, talk to your doctor before restarting treatment.

What are the possible side effects of JUXTAPID?

JUXTAPID can cause serious side effects, including:

- See **“What is the most important information I should know about JUXTAPID?”**
- **problems absorbing certain nutrients.** JUXTAPID may decrease your ability to absorb fat-soluble nutrients such as Vitamin E and fatty acids. You should take supplements each day that contain fat-soluble vitamins. People with bowel or pancreas problems may have an increased chance of not being able to absorb these nutrients. See **“How should I take JUXTAPID?”**
- **gastrointestinal symptoms.** Diarrhea, nausea, vomiting, and stomach pain or discomfort are very common when taking JUXTAPID. Strictly following a low-fat diet may help lower the chance of having these symptoms. Stop taking JUXTAPID and tell your doctor if you have severe diarrhea, especially if you also have lightheadedness, decreased urine output, or tiredness.
- **increased levels of certain blood thinners.** JUXTAPID can increase the level of the blood thinner, warfarin. If you take warfarin, your doctor should check your blood clotting times frequently, especially after your dose of JUXTAPID changes.
- **liver problems caused by certain drugs.** Certain medicines can cause liver problems, including isotretinoin, acetaminophen, methotrexate, tetracyclines, and tamoxifen. If you take these medicines with JUXTAPID your doctor may do blood tests more often to check your liver.

The most common side effects of JUXTAPID include:

- diarrhea
- nausea
- vomiting
- indigestion
- stomach cramping/pain

Tell your doctor if you have any side effect that bothers you or that does not go away.

These are not all the possible side effects of JUXTAPID. For more information, ask your doctor or pharmacist.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store JUXTAPID?

- Store JUXTAPID at room temperature, between 68°F and 77°F (20°C and 25°C).
- Keep JUXTAPID in a tightly closed container.
- Keep JUXTAPID capsules dry.
- Safely throw away medicine that is out of date or no longer needed.

Keep JUXTAPID and all medicines out of the reach of children.

General information about the safe and effective use of JUXTAPID.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use JUXTAPID for a condition for which it was not prescribed. Do not give JUXTAPID to other people, even if they have the same symptoms you have. It may harm them.

This Medication Guide summarizes the most important information about JUXTAPID. If you would like more information, talk with your doctor. You can ask your pharmacist or doctor for information about JUXTAPID that is written for healthcare professionals.

For more information, go to www.JUXTAPID.com or call 1-85-JUXTAPID (1-855-898-2743).

What are the ingredients in JUXTAPID?

Active ingredient: lomitapide mesylate

Inactive ingredients: pregelatinized starch, sodium starch glycolate, microcrystalline cellulose, lactose monohydrate, silicon dioxide, magnesium stearate

Capsule shell: The capsule shells of all strengths contain gelatin and titanium dioxide; the 5 mg, 10 mg and 30 mg capsules also contain red iron oxide; and the 30 mg capsules also contain yellow iron oxide. The imprinting ink contains shellac, black iron oxide, and propylene glycol.

This Medication Guide has been approved by the U.S. Food and Drug Administration.

Manufactured by:



Amryt Pharmaceuticals DAC
Dublin, Ireland US

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