

What is JUXTAPID?

JUXTAPID is a prescription medicine used along with a low-fat diet, exercise, and other low-density lipoprotein cholesterol (LDL-C) lowering medicines to reduce LDL-C cholesterol in adults and children 2 years of age and older with a type of high cholesterol called homozygous familial hypercholesterolemia (HoFH).

HoFH is the more serious and rare form of FH inherited from both parents. Because of the risk of liver problems, JUXTAPID should only be taken by people who have HoFH.

It is not known if JUXTAPID is safe and effective in people with high cholesterol who do not have HoFH, including in people who have heterozygous familial hypercholesterolemia (HeFH) which is the less severe form of FH and only one parent passes it down.

Risk of liver problems with JUXTAPID

JUXTAPID can cause liver problems such as increased liver enzymes or increased fat in the liver.

Your doctor will order blood tests to check your liver:

- before you start JUXTAPID
- if your dose is increased
- monthly during the first year
- every 3 months after the first year

Regular blood test results will tell your doctor if certain liver enzyme levels are higher than normal. Enzyme levels higher than normal can be an early sign of liver problems. If your tests show signs of liver problems, your doctor may reduce your dose or stop it.

JUXTAPID may cause other side effects. Talk to your doctor about the other risks associated with JUXTAPID.

What should I do?

Before you start treatment with JUXTAPID, tell your doctor if you have had liver problems, including liver problems while taking other medicines.

While you are taking JUXTAPID, tell your doctor right away if you have any of these symptoms of liver problems:

- nausea, vomiting, or stomach pain that gets worse, changes, or does not go away
- fever
- flu-like symptoms
- yellowing of your eyes or skin
- feeling more tired than usual

JUXTAPID can cause nausea, vomiting, stomach pain, diarrhea, and flatulence (gas), especially if you do not eat a low-fat diet. Some of these side effects can also be symptoms of liver problems so you should tell your doctor.

Drinking alcohol may increase your chance of having liver problems or make your liver problems worse. Limit the amount of alcohol you drink (no more than 1 drink per day). One drink can be either a 12-ounce beer, a 5-ounce glass of wine, or 1.5 ounces of liquor.

You should avoid food or drinks with grapefruit while taking JUXTAPID.

Keep a list of all the medicines you take including prescription and over-the-counter medicines, vitamins, and herbal supplements.

Keep your doctor and your pharmacist informed. Some medicines, when taken together, can overwork the liver and cause problems.

Your doctor will ask you to take certain vitamin supplements each day to make sure you get all the nutrients you need.

Take your JUXTAPID capsule whole with water at least 2 hours after your evening meal every day.



Instructions for Prescribers

The form must be signed by both the prescriber and patient. Provide a copy of the signed form to the patient.

PATIENT ACKNOWLEDGEMENT

Patient First Name: _____ Middle Initial: ____ Last Name: _____
City: _____ State: _____ Zip: _____
Phone: _____ Email: _____
Date of Birth: _____ Gender: Male Female Decline to Identify

I have received the **Patient Guide** from my prescriber.
I understand that:

- JUXTAPID is a prescription medicine used along with a low-fat diet, exercise, and other low-density lipoprotein cholesterol (LDL-C) lowering medicines to reduce LCL-C in adults and children 2 years of age and older with a type of high cholesterol called homozygous familial hypercholesterolemia (HoFH).
- JUXTAPID may cause serious side effects including liver problems such as increased liver enzymes or increased fat in the liver.
- Because of these side effects, JUXTAPID is only for people with homozygous familial hypercholesterolemia (HoFH).
- I will enroll in the JUXTAPID REMS by completing the Patient-Prescriber Acknowledgement Form.
- I will need to have blood tests to check my liver:
 - before I start JUXTAPID
 - if my dose is increased
 - monthly during the first year
 - every three months after the first year
- If my tests show liver problems, my doctor may lower my dose of JUXTAPID or stop it.
- I will tell my doctor if I have any of the following symptoms:
 - nausea, vomiting, or stomach pain that gets worse, changes, or does not go away
 - fever
 - flu-like symptoms
 - yellowing of my eyes or skin
 - feeling more tired than usual

Patient Signature: _____ **Date:** _____

PRESCRIBER ACKNOWLEDGEMENT

Prescriber First Name: _____ Middle Initial: ____ Last Name: _____
Address: _____
City: _____ State: _____ Zip: _____
Office Phone: _____ NPI #: _____

- I have counseled the patient on the indication and risks of JUXTAPID, including the risk of liver problems, and the need for periodic liver monitoring.
- I have reviewed the **Patient Guide** with the patient and provided a signed copy of this form to the patient.
- I discussed all concerns and answered all questions the patient had about treatment with JUXTAPID.

Prescriber Signature: _____ **Date:** _____

IMPORTANT

REVIEW TO ENSURE ALL FIELDS ARE COMPLETED | FAX TO 1-855-898-2498

If you have any questions, please contact the JUXTAPID REMS Coordinating Center.
Phone: 1-85-JUXTAPID (1-855-898-2743) | Fax: 1-855-898-2498 | www.juxtapidREMSprogram.com