

What is JUXTAPID?

JUXTAPID is a prescription medicine used along with a low-fat diet and other cholesterol-lowering treatments, including low-density lipoprotein apheresis where available, to lower different forms of cholesterol in people with homozygous familial hypercholesterolemia (HoFH).

Because of the risk of liver problems, JUXTAPID should only be taken by people with 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).

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, and while you are taking JUXTAPID.

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 JUXTAPID altogether.

There are other side effects associated with the use of JUXTAPID. Talk to your doctor about the other risks associated with JUXTAPID.

What is the JUXTAPID Risk Evaluation and Mitigation Strategy (REMS) Program?

Because of the risk of liver damage with JUXTAPID, the Food and Drug Administration (FDA) has required a special program called a Risk Evaluation and Mitigation Strategy (REMS) for JUXTAPID. The JUXTAPID REMS Program is designed to educate patients and healthcare providers about the appropriate use of JUXTAPID, the risk of liver damage when taking JUXTAPID, and the need for regular monitoring of your liver.

As part of the REMS Program, your doctor will discuss the risks of JUXTAPID with you and give you this Patient Guide.

Both you and your prescriber must sign the attached JUXTAPID REMS Program Patient-Prescriber Acknowledgement Form for you to receive JUXTAPID. Your prescriber will provide a copy of the signed form to the JUXTAPID REMS Program.

The JUXTAPID REMS Program also requires JUXTAPID to be dispensed by a REMS-certified specialty pharmacy. Your doctor will send your prescription to the certified specialty pharmacy, who will contact you if they need further information.

What do I need to 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 the following symptoms, as these may be signs of liver problems:

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

JUXTAPID can 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.

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.

Keep track of all the medications you are taking, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Make sure to keep your doctor and your pharmacist informed. Some medications, when taken together, can overwork the liver and cause problems.

Where can I get more information about the JUXTAPID REMS Program?

If you would like more information, talk to your doctor or visit www.juxtapidREMSprogram.com

Notes:



Instructions for Prescribers

The form must be signed by both the prescriber and patient. If the patient is under the age of 18 years, the form must be signed by their parent or legal guardian.* Fax the completed form to the JUXTAPID REMS Program at 1-855-898-2498. Provide a copy of the form to patient.

PATIENT ACKNOWLEDGEMENT

Patient First Name: _____ Middle Initial: _____ Last Name: _____
City: _____ State: _____ Zip: _____

I have received, read, and understand the JUXTAPID REMS Program Patient Guide with my prescriber and I understand that:

- JUXTAPID is used along with diet and other lipid-lowering treatments 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)

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 need to have blood tests to check my liver before I start and during JUXTAPID therapy. If my tests show liver problems, my doctor may lower my dose of JUXTAPID or stop it.

Patient Signature: _____ Date: _____

*Parent or Guardian Signature: _____ Date: _____

Parent or Guardian Name: _____

PRESCRIBER ACKNOWLEDGEMENT

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

- I have counseled the patient (parent/guardian when appropriate) on the indication and risks of JUXTAPID, including the risk of liver problems, and the need for periodic monitoring.
I have reviewed the JUXTAPID REMS Program Patient Guide with the patient (and parent/guardian when appropriate) 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: _____