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 hypercholesterolemia (HoFH). It is not known if JUXTAPID is effective in people with high cholesterol, HoFH, including in people with familial hypercholesterolemia.

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 REMS program is designed to educate healthcare providers about the use of JUXTAPID, the risk of liver problems with JUXTAPID, and the need for monitoring of your liver.

Under the REMS program, your doctor will give you a copy of the JUXTAPID REMS Patient Prescriber Acknowledgement Form. Your prescriber must sign the form and give it to you. You must sign the form and give it to your pharmacist. Your pharmacist will give it to the pharmacy where you 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 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

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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.

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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:

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