

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

Pr **JUXTAPID**®

lomitapide capsules

Read this carefully before you start taking **JUXTAPID** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **JUXTAPID**.

What is JUXTAPID used for?

JUXTAPID is used to lower blood cholesterol levels in adults with homozygous familial hypercholesterolemia (HoFH). This is a genetic condition where high blood cholesterol is inherited from both parents. JUXTAPID is used in combination with a low-fat diet and other fat-lowering medicines, with or without LDL apheresis (a procedure used to remove “bad” cholesterol from the blood).

How does JUXTAPID work?

JUXTAPID works by blocking the action of microsomal triglyceride transfer proteins (MTPs). These proteins are located within the liver and gut cells. They are involved in assembling fatty substances into larger particles that are then released into the blood stream. By blocking these proteins, the medicine decreases the level of fats and cholesterol in the blood. This helps to control the disease process.

What are the ingredients in JUXTAPID?

Medicinal ingredients: Lomitapide mesylate

Non-medicinal ingredients: Gelatin, lactose white monohydrate, magnesium stearate, microcrystalline cellulose, pregelatinized starch, red iron oxide (5mg and 10 mg capsules only), silicon dioxide, sodium starch glycolate and titanium dioxide.

JUXTAPID comes in the following dosage forms:

Capsules; 5 mg, 10 mg, 20 mg

Do not use JUXTAPID if:

- You have liver problems or have been told by a healthcare professional you have unexplained abnormal liver tests.
- You have bowel problems (such as inflammatory bowel disease) or cannot absorb food properly from your bowel.
- You are taking more than 20 mg simvastatin daily, unless you have been instructed by your healthcare professional to take 40 mg simvastatin daily, and previously tolerated it well.

- You are taking medicines known as moderate or strong CYP3A4 inhibitors (e.g., certain medicines used to treat bacterial, fungal, or viral infections, as well as certain medicines used to treat depression, high blood pressure, or chest pain). These medicines may affect how your body breaks down JUXTAPID.
- You are pregnant, trying to get pregnant, or think you may be pregnant.
- You are allergic to lomitapide or any of the other ingredients in JUXTAPID or its packaging.
- You have one of the following rare hereditary diseases:
 - Galactose intolerance
 - Lapp lactase deficiency
 - Glucose-galactose malabsorption
 because lactose is a non-medicinal ingredient in JUXTAPID.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take JUXTAPID. Talk about any health conditions or problems you may have, including if you:

- take medicines or foods that may increase the level of JUXTAPID in your blood and make side effects more likely, such as:
 - grapefruit juice. Do not drink it while taking JUXTAPID.
 - statins, which are medicines used to lower blood cholesterol levels. These include atorvastatin, fluvastatin, lovastatin, pravastatin, rosuvastatin and simvastatin.
 - warfarin, a blood thinner. Your healthcare professional may adjust your dose and monitor you more frequently if you start taking JUXTAPID.
- are elderly
- take diuretics (“water pills”), which are medicines used to treat high blood pressure
- take medicines or foods that have the potential to damage your liver, such as:
 - isotretinoin - used to treat severe acne
 - amiodarone - used to prevent and treat an abnormal heart rhythm
 - high dose of acetaminophen - used to treat fever and pain
 - methotrexate - used to treat certain types of cancer
 - tetracyclines - used to treat bacterial infections
 - tamoxifen - used to treat breast cancer
 - alcoholic drinks

Other warnings you should know about:

JUXTAPID can cause serious side effects, including:

- **Muscles disorders, including rhabdomyolysis** (breakdown of damaged muscle): Taking JUXTAPID with statins may increase your risk of a serious muscle problem. Your healthcare professional may adjust your dose while you take JUXTAPID. Tell your healthcare professional right away if you experience unexplained muscle pain, tenderness, weakness, or dark urine while taking JUXTAPID.
- **Severe diarrhea and/or dehydration:** JUXTAPID may cause severe diarrhea and dehydration. This can lead to low blood pressure and volume, especially if you are elderly or take diuretics (“water pills”).
- **Liver disorders/damage:** JUXTAPID may cause liver damage and a fatty liver. The chance of liver damage is higher if you take statins, such as atorvastatin or simvastatin.

Drinking alcohol may also raise your chance of liver damage. You should not have more than one alcoholic drink per day when you take JUXTAPID. Your healthcare professional may do blood tests before you start taking JUXTAPID, when your dose is increased, and regularly during your treatment to check if your liver is working properly. Depending on your test results, your healthcare professional may adjust your dose, temporarily stop or discontinue your treatment with JUXTAPID.

See the **What are possible side effects from using JUXTAPID** for more information on these and other serious side effects.

Pregnancy and birth control:

- JUXTAPID should **not** be taken during pregnancy. It may cause birth defects and harm an unborn baby. Your healthcare professional will discuss the potential risks with you.
- If you are a woman who could become pregnant, your healthcare professional will test you for pregnancy before prescribing JUXTAPID. Your pregnancy test must be negative for you to take JUXTAPID.
- Use a highly effective birth control method while you are taking JUXTAPID. Do not have unprotected sex. Birth control pills may not work as well if you have diarrhea or vomiting. If you use birth control pills, use an additional form of birth control while you are taking JUXTAPID.
- If you discover that you are pregnant while taking JUXTAPID, **stop** taking the medicine and contact your healthcare professional **as soon as possible**.

Breastfeeding:

- It is not known if JUXTAPID can pass into breast milk and harm a breastfed baby. Therefore, JUXTAPID is **not** recommended during breastfeeding.
- You and your healthcare professional will decide if you should take JUXTAPID or breastfeed. You should not do both.

Check-ups and testing: Your healthcare professional will regularly monitor and assess your health before and while you are taking JUXTAPID. This may include blood tests.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

Serious Drug Interactions

Do not take JUXTAPID with:

- more than 20 mg simvastatin daily, unless you have been instructed by your healthcare professional to take 40 mg simvastatin daily, and previously tolerated it well.
- moderate or strong CYP3A4 inhibitors (e.g., certain medicines used to treat bacterial, fungal, or viral infections, as well as certain medicines used to treat depression, high blood pressure, or chest pain). These medicines may affect how your body breaks down JUXTAPID.

Taking JUXTAPID with any of these medicines may cause serious drug interactions. Ask your healthcare professional if you are unsure you are taking these medicines.

The following may interact with JUXTAPID:

- itraconazole, fluconazole, ketoconazole or posaconazole - used to treat fungal infections
- erythromycin, clarithromycin, telithromycin, tetracyclines, azithromycin or isoniazid - used to treat bacterial infections
- indinavir, nelfinavir, tipranavir/ritonavir, saquinavir or maraviroc - used to treat HIV/AIDS
- diltiazem, verapamil, diuretics ("water pills"), amlodipine, aliskiren, ambrisentan or talinolol - used to treat high blood pressure
- nefazodone, fluoxetine, fluvoxamine or alprazolam - used to treat depression or other mental disorders
- dronedarone or amiodarone - used to treat an abnormal heart rhythm
- statins, such as atorvastatin, fluvastatin, lovastatin, pravastatin, rosuvastatin and simvastatin, or bile acid resins, such as colestesvelam and cholestyramine - used to treat high blood cholesterol. Do not take more than 20 mg simvastatin daily, unless you have been instructed by your healthcare professional to take 40 mg simvastatin daily, and previously tolerated it well.
- methotrexate, tamoxifen, bicalutamide, lapatinib, nilotinib, pazopanib, everolimus, imatinib or topotecan - used to treat cancer
- cyclosporine or sirolimus - used to suppress your immune system
- saxagliptin or sitagliptin - used to control high blood sugar
- cimetidine or ranitidine - used to treat ulcers of the stomach and intestines
- warfarin - a blood thinner
- dabigatran - used to treat and prevent blood clots
- colistazol - used to improve blood flow
- ticagrelor - used to prevent heart attack and stroke
- digoxin - used to treat various heart conditions
- isotretinoin - used to treat severe acne
- high dose of acetaminophen - used to treat pain and fever
- tolvaptan - used to treat low blood sodium
- zileuton - used to treat asthma
- colchicine - used to treat gout
- ranolazine - used to treat chest pain
- fexofenadine - used to relieve allergies
- birth control pills

- ginkgo or goldenseal - herbal products
- peppermint oil
- alcoholic beverages
- grapefruit juice or Seville oranges

How to take JUXTAPID:

- Take JUXTAPID:
 - exactly as your healthcare professional tells you.
 - once a day, with a glass of water. Swallow capsules whole. Do not open, crush, dissolve or chew capsules.
 - on an empty stomach, at least 2 hours after the evening meal. Taking JUXTAPID with food may cause gastrointestinal problems, such as diarrhea, vomiting, abdominal pain or cramps, indigestion or gas.

- Your healthcare professional will ask you to:
 - take other fat-lowering medicines with JUXTAPID
 - start a low-fat diet before taking JUXTAPID and during your treatment. This will help reduce your risk of experiencing the gastrointestinal problems described above.

Your healthcare professional may also ask you to undergo LDL apheresis, a procedure used to remove bad cholesterol from your blood. Continue these treatments as prescribed by your healthcare professional.

- JUXTAPID makes it harder for some fat-soluble nutrients, such as vitamin E and fatty acids, to get into your body. Your healthcare professional may prescribe you supplements for you to take each day while you take JUXTAPID. These should not be taken at the same time as JUXTAPID. Always take these supplements at least two hours before or after a JUXTAPID dose. It is recommended that dietary supplements be taken in the morning. Your healthcare professional will tell you how to add them to your diet.

Usual dose of dietary supplements:

Daily Amount	
Vitamin E	400 IU
Omega-3:	
Eicosapentaenoic acid (EPA)	110 mg
Docosahexaenoic acid (DHA)	80 mg
Alpha linoleic acid (ALA)	210 mg
Omega-6: Linoleic acid	200 mg

Usual dose:

- The starting dose is 5 mg once a day.
- Your healthcare professional may increase your dose after two weeks and, then again after every 4 weeks.
- Maximum dose: 60 mg a day.

Overdose:

If you think you, or a person you are caring for, have taken too much JUXTAPID, contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

Missed Dose:

If you miss a dose, take your normal dose at the usual time the next day. Do not double the dose to make up for the missed dose. If your dosing has been interrupted for more than a week, contact your healthcare professional before restarting JUXTAPID.

What are possible side effects from using JUXTAPID?

These are not all the possible side effects you may have when taking JUXTAPID. If you experience any side effects not listed here, tell your healthcare professional.

Side effects may include:

- chest pain
- flu (fever, tiredness, body aches)
- cold (sore throat, stuffy or runny nose)
- fatty liver

JUXTAPID can cause abnormal blood test results. Your healthcare professional will decide when to perform blood tests and will interpret the results.

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
COMMON			
Gastrointestinal Disorders: Nausea, vomiting, diarrhea, flatulence, stomach cramping or pain, indigestion, decreased appetite, belching or burping	√		
Muscle disorders, including rhabdomyolysis (breakdown of damaged muscle): Muscle pain or spasm that you cannot explain, muscle tenderness or weakness, dark brown urine		√	
UNCOMMON			
Alopecia (hair loss): hair falling out in large clumps, burning sensation of the scalp	√		

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
Liver Disorder / Damage: yellowing of the skin or eyes, fever, dark urine, pale stools, loss of appetite, abdominal pain, nausea, or vomiting that gets worse, does not go away or changes		√	
Severe diarrhea and/or dehydration: associated with lightheadedness, thirst, headache, loss of appetite, decreased urination, confusion or unexplained tiredness			√
Weight loss	√		

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

- Store at room temperature (15°C to 30°C).
- Keep bottle tightly closed in order to protect from moisture.
- Keep out of reach and sight of children.

If you want more information about JUXTAPID:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website:

(<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>); by calling 1-800-696-1341, or by mailing Chiesi Farmaceutici S.p.A. at the following address:

- Chiesi Farmaceutici S.p.A.
Via Palermo 26/A, 43122 Parma, Italy

This leaflet was prepared by Chiesi Farmaceutici S.p.A.

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