Lojuxta® ▼ (lomitapide) capsules

Patient care guide

This document provides important information about some of the side effects of Lojuxta, what action you can take to prevent them and what you should do if you experience them.

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get.

If you get any side effects, talk to your healthcare professional. This includes any possible side effects not listed in the Patient Information Leaflet (PIL). In the UK, you can also report side effects directly via the Yellow Card Scheme at **https://yellowcard.mhra.gov.uk/**

By reporting side effects, you can help provide more information on the safety of this medicine. Side effects should also be reported to Chiesi Limited on **0800 0092329** or e-mail: **PV.UK@chiesi.com**

Chiesi
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Read the Lojuxta patient information leaflet

You should also read the patient information leaflet which is inside each pack of Lojuxta.

It is important that you read the leaflet before you start taking this medicine and each time you get a new pack of Lojuxta as it could contain new information.

Your Alert card

You have been given a Lojuxta Alert card

The purpose of the Alert card is to inform healthcare professionals (doctors, nurses, dentists and pharmacists) before they prescribe any other drug for you, that you are taking Lojuxta and that this could interact with other drugs. This includes medications that you may buy without a prescription.

It is essential that you carry your card with you at all times while taking your treatment.

What is Lojuxta and how does it work?

Your doctor has prescribed Lojuxta for you. It is a prescription-only medicine for adults with homozygous familial hypercholesterolaemia (also known as HoFH).

HoFH is an uncommon condition inherited from both parents that leads to high levels of cholesterol in your blood. The liver of someone with HoFH has trouble removing unused cholesterol from the blood. This means that the bad (LDL) cholesterol can build up in arteries, creating plaque that narrows your blood vessels and can cause heart disease.

Lojuxta contains an active substance called lomitapide which works by blocking a protein responsible for cholesterol being formed in the liver and fats being absorbed by the gut.

By blocking this protein, Lojuxta reduces the level of fat and cholesterol in the blood.

Lojuxta can lower blood levels of:

- total cholesterol (the measure of all the fats in your blood)
- low density lipoprotein (LDL) cholesterol (or the 'bad' cholesterol)
- apolipoprotein-B (a protein that carries 'bad cholesterol' in the blood), and
- triglycerides (another type of fat carried in the blood).

This medicine is used along with a low-fat diet and other lipid-lowering treatments.

Effect on the liver 4

Lojuxta in pregnancy 5

Interactions with other medicines 6

How to take Lojuxta 7

Dietary requirements 8

Enrolling in the Lojuxta Registry 8

Important possible side effects

Further monitoring is being carried out on this medicine. This will allow us to quickly identify new safety information about it. You can help by reporting any side effects you may get to your doctor.

Effect on the liver

Because of how it works through the liver, Lojuxta may cause liver problems. Before taking this medicine, you should tell your doctor if you have had liver disorders in the past. You must **not** take Lojuxta if you have any problems with your liver or have had an abnormal blood test of your liver in the past that cannot be explained.

You must tell your doctor about all other medications that you are taking. If you take other drugs which can cause liver problems, your doctor will take special care in prescribing this medicine.

There are some symptoms that may indicate you have liver problems. Tell your doctor right away if you have nausea, vomiting, or stomach pain that gets worse, does not go away, or changes.

Also, tell your doctor right away if you have any of these symptoms.

- Fever
- Your skin or the whites of your eyes turning yellow
- Being more tired than usual
- Feeling like you have the flu

Although these symptoms can be due to other causes, it is important that you do not ignore them in case they are due to your liver.

Your doctor will do a blood test to check your liver:

- before you start taking Lojuxta
- if they increase your dose, and
- regularly during treatment.

The results of these blood tests will help your doctor to know if they need to adjust your dose of Lojuxta. If your tests show some liver problems, your doctor may decide to reduce your dose or stop the treatment. Your doctor will also ask you to have further tests once a year. These will include extra blood tests and other tests, such as a scan, to monitor your liver. Your doctor will discuss these tests with you.

It is also recommended that you do not drink alcohol while taking Lojuxta as this can increase the risk of damage to your liver.

Lojuxta in pregnancy

Lojuxta is not safe to be used in pregnancy. In some non-clinical trials carried out on animals, Lojuxta affected the normal development of their young. There is no information on the effects of Lojuxta in pregnant humans.

Do **not** take this medicine if you are pregnant, trying to get pregnant, or think you may be pregnant, as there is a possibility that it could harm your unborn baby. If you get pregnant while taking this medicine, call your doctor immediately and stop taking t he capsules.

Before starting treatment you should confirm you are not pregnant and that you are using effective contraception, as advised by your doctor, as there is a possibility that Lojuxta could harm your unborn baby.

Lojuxta can cause diarrhoea and vomiting. If this happens and lasts more than two days and you use contraceptive pills, you must use an alternative method of contraception (for example condoms or a diaphragm) and continue using it for seven days after you have recovered.

If, after you have started treatment with Lojuxta, you decide that you would like to become pregnant, please tell your doctor, as he will need to change your treatment.

Interactions with other medicines

Lojuxta may interact with a number of medicines and there are some drugs that you must never take with Lojuxta. It is extremely important that, before you take Lojuxta, you tell your doctor if you are taking, have recently taken or might take any other medicines. If while on Lojuxta you are given a prescription for a new medicine or buy a medicine over the counter, you should check that you can take it safely while on Lojuxta.

The drugs that Lojuxta may interact with also include some drugs used to treat the following.

- Fungal infections
- High blood pressure or angina, or to regulate heart rhythm
- HIV infection
- Blood clots (or to prevent them)
- Epilepsy
- Tuberculosis
- Diabetes
- Anxiety and depression
- Severe acne
- Cystic fibrosis
- Excessive sleepiness in the daytime
- Bladder incontinence
- Cushing's syndrome
- Low blood sodium levels
- Gout
- Hay fever

You should also tell your doctor if you are taking, have recently taken or might take any of the following.

- Antibiotics
- Oral contraceptives
- Steroids
- Anti-cancer drugs and drugs to treat nausea and vomiting in cancer
- Drugs which alter the immune system
- Drugs to reduce stomach acid

- Drugs to lower cholesterol (statins) and in particular simvastatin. The risk of liver damage is increased when Lojuxta is used at the same time as statins. Muscle aches and pains (myalgia) or weakness (myopathy) may also occur. **Contact your doctor immediately if you experience any unexplained muscle aches and pains, tenderness or weakness.** You should not take more than 40 mg of simvastatin when using Lojuxta.

Some drugs and herbal medicines that you can buy without a prescription may also interact with Lojuxta. You should tell your doctor if you are taking, have recently taken or might take any of the following.

- Any medicines containing paracetamol (to treat pain)
- St John's wort (for depression)
- Ginko (to improve memory)
- Goldenseal (for inflammation and infection)

Do not drink grapefruit juice if you have been prescribed Lojuxta as this can also interact with your medicine.

How to take Lojuxta

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure. The recommended starting dose is a 5 mg capsule each day. Your doctor may increase your dose slowly over time, up to 60 mg each day. Your doctor will tell you:

- what dose to take and for how long, and
- when to increase or decrease your dose.

Do not change the dose yourself.

Take this medicine once a day at bedtime with water at least two hours after your evening meal. Do not take this medicine with food, as this can cause stomach problems including nausea, vomiting and diarrhoea.

If you take another medicine that lowers cholesterol by binding bile acids, such as colesevelam or cholestyramine, take that medicine at least **four hours before or four hours after** you take Lojuxta.

Because of the possibility of interactions with other medications, your doctor may change the time of day you take your medications. Alternatively, your doctor may decrease your dose of Lojuxta. Inform your doctor of any change in the medications you are taking.

Dietary requirements

Because Lojuxta reduces the absorption of fats in the gut, you need to take specific amounts of vitamin E and essential fatty acids each day while you take Lojuxta. Take your dietary supplements as directed by your doctor or the pharmacist.

These supplements include the following.

- Vitamin E - 400 international units (IU)
- Omega-3
    - EPA – approximately 110 mg
    - DHA – approximately 80 mg
    - ALA – approximately 210 mg
- Omega-6
    - Linoleic acid – approximately 200 mg

As Lojuxta reduces the absorption of fats, some fats in the diet pass through your intestines unabsorbed. Lojuxta may cause diarrhoea, nausea and vomiting, and stomach pain or discomfort. Strictly following a recommended eating plan, which focuses on limiting the total amount of fat you eat, should lower the chance of having these symptoms. Before starting Lojuxta, it is very important that you understand the low-fat eating plan that has been recommended for you.

It is recommended that you limit the amount of total fat you eat to less than 20% of your total calorie intake while taking Lojuxta. Ask your doctor about talking to a dietitian to advise you on what to eat and not to eat.

Enrolling in the Lojuxta Registry

A patient registry has been set up to collect medical information on patients treated with Lojuxta. This is a type of study which will help us to learn more about any long-term effects of Lojuxta. If you

agree to take part in this study you do not have to make any extra visits to your doctor or have any further investigations, and your treatment will always be what your doctor considers to be best for you.

The registry is very important as it will collect information on a large number of patients over a longer period of time than has been studied in clinical trials. This will provide valuable information on the long-term safety and effectiveness of Lojuxta.

The aim is to enrol all patients treated with Lojuxta into the registry. You should discuss this with your doctor, who has also been asked to take part in the registry. We will only collect your information if you give your agreement, in writing, to be enrolled. You will not be able to be identified from the information you provide.

We very much hope you will agree to taking part in the study. However, if you decide not to take part, this will not affect the care you receive from your doctor. If your doctor considers Lojuxta to be the right treatment for you, they will still prescribe this for you and look after you in just the same way.

Notes

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