

PACKAGE LEAFLET

Package leaflet: Information for the user

Lojuxta 5 mg hard capsules
Lojuxta 10 mg hard capsules
Lojuxta 20 mg hard capsules
lomitapide

▼ 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. See the end of section 4 for how to report side effects.

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Lojuxta is and what it is used for
2. What you need to know before you take Lojuxta
3. How to take Lojuxta
4. Possible side effects
5. How to store Lojuxta
6. Contents of the pack and other information

1. What Lojuxta is and what it is used for

Lojuxta contains the active substance called lomitapide. Lomitapide is a “lipid-modifying agent” which works by blocking the action of “microsomal triglyceride transfer protein.” This protein is located within the liver and the gut cells, where it is involved in assembling fatty substances into larger particles that are then released into the blood stream. By blocking this protein, the medicine decreases the level of fats and cholesterol (lipids) in the blood.

Lojuxta is used to treat adult patients with very high cholesterol because of a condition that runs in their families (homozygous familial hypercholesterolaemia or HoFH). It is typically passed down by both father and mother, who also have high cholesterol passed down from their parents. The patient’s “bad” cholesterol level is very high from a very early age. The “bad” cholesterol can lead to heart attacks, strokes or other events at an early age. Lojuxta is used with a low-fat diet and other lipid lowering treatments to decrease your cholesterol levels.

Lojuxta can lower blood levels of:

- low density lipoprotein (LDL) cholesterol (“bad” cholesterol)
- total cholesterol
- apolipoprotein-B, a protein that carries “bad cholesterol” in the blood
- triglycerides (fat carried in the blood)

2. What you need to know before you take Lojuxta

Do not take Lojuxta:

- if you are allergic to lomitapide or any of the other ingredients of this medicine (listed in section 6).
- if you have liver problems or unexplained abnormal liver tests.
- if you have bowel problems or cannot absorb food from your bowel.
- if you take more than 40 mg of simvastatin daily (another medicine used to lower cholesterol).
- if you take any of these medicines that affect the way lomitapide is broken down in the body:
 - itraconazole, ketoconazole, fluconazole, voriconazole, posaconazole (for fungal infections) ;
 - telithromycin, clarithromycin, erythromycin (for bacterial infections)
 - indinavir, nelfinavir, saquinavir (for HIV infection) ;
 - diltiazem, verapamil (for high blood pressure, or angina), and dronedarone (to regulate heart rhythm).
- if you are pregnant, trying to get pregnant, or think you may be pregnant (see section 2 under ‘Pregnancy and breast-feeding’).

Warnings and precautions

Talk to your doctor or pharmacist before taking Lojuxta if you:

- have had liver problems, including liver problems whilst taking other medicines. These capsules may cause side effects which can also be symptoms of liver problems. These side-effects are listed in section 4 and you must **tell your doctor immediately** if you have any of these signs and symptoms, as they may be caused by liver damage. Your doctor will give you a blood test to check your liver before you start taking these capsules, if your dose is increased, and regularly during treatment. These blood tests help your doctor adjust your dose. If your tests show some liver problems, your doctor may decide to reduce your dose or stop the treatment.

You may in some cases experience loss of fluids/dehydration, e.g. in case of vomiting, nausea and diarrhoea. It is important to avoid dehydration by drinking enough fluids (see section 4).

Children and adolescents

No studies have been conducted in children and adolescents under the age of 18. Therefore the use of this medicine in children and adolescents is not recommended.

Other medicines and Lojuxta

Tell your doctor or pharmacist if you are taking, have recently taken, or might take any other medicines.

Other medicines may affect the way Lojuxta works. Do not take any of the following medicines with Lojuxta:

- some medicines for bacterial, fungal or HIV infection (see section 2 under ‘Do not take Lojuxta’)
- some medicines for high blood pressure, angina or to regulate heart rhythm (see section 2 under: ‘Do not take Lojuxta’)

You must also tell your doctor or pharmacist if you are taking any of the following medicines, as they may need to change your dose of Lojuxta:

- medicines which lower cholesterol (e.g. atorvastatin)
- combined oral contraceptives (e.g. ethinylestradiol, norgestimate)
- glucocorticoids (e.g. beclometasone, prednisolone) steroid medicines used to treat inflammation in conditions such as severe asthma, arthritis
- medicines to treat cancer (e.g. bicalutamide, lapatinib, methotrexate, nilotinib, pazopanib, tamoxifen) or nausea/vomiting with cancer treatment (e.g. fosaprepitant)

- medicines to reduce the activity of the immune system (e.g. ciclosporin, tacrolimus)
- medicines to treat bacterial or fungal infections (e.g. nafcillin, azithromycin, roxithromycin, clotrimazole)
- medicines to treat and prevent blood clots (e.g. cilostazol, ticagrelor)
- medicines to treat angina – chest pain caused by the heart (e.g. ranolazine)
- medicines to reduce blood pressure (e.g. amlodipine, lacidipine)
- medicines to regulate heart rhythm (e.g. amiodarone)
- medicines to treat epilepsy (e.g. phenobarbital, carbamazepine, phenytoin)
- medicines to treat diabetes (e.g. pioglitazone, linagliptin)
- medicines to treat tuberculosis (e.g. isoniazid, rifampicin)
- tetracycline antibiotics to treat infections such as urinary tract infections
- medicines to treat anxiety disorders and depression (e.g. alprazolam, fluoxetine, fluvoxamine)
- antacids (e.g. ranitidine, cimetidine)
- aminoglutethimide – a medicine used to treat Cushing’s syndrome
- medicines to treat severe acne (e.g. isotretinoin)
- paracetamol – to treat pain
- medicines to treat cystic fibrosis (e.g. ivacaftor)
- medicines to treat urinary incontinence (e.g. propiverine)
- medicines to treat low levels of sodium in the blood (e.g. tolvaptan)
- medicines to treat excessive daytime sleepiness (e.g. modafinil)
- some herbal medicines:
 - St. John’s Wort (for depression)
 - Ginkgo (to improve memory)
 - Goldenseal (for inflammation and infection)

Lojuxta may affect the way other medicines work. Tell your doctor or pharmacist if you are taking any of the following medicines:

- oral contraceptives (see section 2 under ‘Pregnancy and breast-feeding’)
- other medicines used to lower cholesterol such as:
 - statins such as simvastatin. The risk of liver damage is increased when this medicine 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 (see section 2 under ‘Do not take Lojuxta’)
- coumarin anticoagulants for thinning the blood (e.g. warfarin)
- medicines to treat cancer (e.g. everolimus, imatinib, lapatinib, nilotinib, topotecan)
- medicines to reduce the activity of the immune system (e.g. sirolimus)
- medicines to treat HIV (e.g. maraviroc)
- medicines to treat and prevent blood clots (e.g. dabigatran etexilate)
- medicines to treat angina – chest pain caused by the heart (e.g. ranolazine)
- medicines to reduce blood pressure (e.g. talinolol, aliskiren, ambrisentan)
- medicines to regulate heart rhythm (e.g. digoxin)
- medicines to treat diabetes (e.g. saxagliptin, sitagliptin)
- medicines to treat gout (e.g. colchicine)
- medicines to treat low blood sodium level (e.g. tolvaptan)
- anti-histamine medicines to treat hayfever (e.g. fexofenadine)

Lojuxta with food, drink and alcohol

- Do not drink any type of grapefruit juice.
- The use of alcohol during Lojuxta treatment is not recommended.
- Your dose of Lojuxta may need to be adjusted if you consume peppermint oil or Seville oranges.

- To lower the chance of stomach problems, you must stay on a low-fat diet whilst taking this medicine. Work with a dietitian to learn what you can eat while taking Lojuxta.

Pregnancy and breast-feeding

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 an unborn baby. If you get pregnant while taking this medicine, call your doctor immediately and stop taking the capsules.

Pregnancy

- Before starting treatment you should confirm you are not pregnant and are using effective contraception, as advised by your doctor. If you use contraceptive pills and suffer from an episode of diarrhoea or vomiting that lasts more than 2 days, you must use an alternative method of contraception (e.g. condoms, diaphragm) for 7 days following resolution of symptoms.
- If, after you have started treatment with Lojuxta, you decide that you would like to become pregnant, please inform your doctor, as your treatment will need to be changed.

Breast-feeding

- It is not known if Lojuxta is passed into breast milk. Please tell your doctor if you are breast-feeding or planning to breast-feed. Your doctor may advise you to stop taking Lojuxta or to stop breast-feeding.

Driving and using machines

Your treatment may affect your ability to drive or use machines. If you feel dizzy during treatment then do not drive or use machines until you feel better.

Lojuxta contains lactose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

3. 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. These capsules should be given to you by a doctor experienced in the treatment of lipid disorders who will also monitor you regularly.

The recommended starting dose is a 5 mg capsule each day. Your doctor may increase your dose slowly over time, up to a maximum of 60 mg each day. Your doctor will tell you:

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

Do not change the dose yourself.

- Take this medicine once a day at bedtime with a glass of water at least 2 hours after your evening meal (see section 2 under ‘Lojuxta with food, drink and alcohol’).
- Do not take this medicine with food, as taking these capsules with food can cause stomach problems.
- If you take another medicine that lowers cholesterol by binding bile acids, such as colesevelam or cholestyramine, take the medicine that binds bile acids at least **4 hours before or 4 hours after** you take Lojuxta.

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

You also need to take daily vitamin E and essential fatty acid (omega-3 and omega-6) supplements while taking this medicine. The usual dose that you will need to take is listed below. Ask your doctor, or dietitian how to obtain these supplements. See section 2 under 'Lojuxta with food, drink and alcohol'.

Daily Amount	
Vitamin E	400 IU*
Omega-3	Approximately
EPA	110 mg*
DHA	80 mg
ALA	210 mg
Omega-6	
Linoleic acid	200 mg

* IU – international units, mg - milligrams

If you take more Lojuxta than you should

Contact your doctor or pharmacist immediately.

If you forget to take Lojuxta

Just take your normal dose at the usual time the next day. Do not take a double dose to make up for a forgotten dose.

If you stop taking Lojuxta

If you stop taking this medicine your cholesterol may rise again. You should contact your doctor before you stop taking this medicine.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Serious side effects:

- abnormal blood tests for liver function have been reported commonly (may affect up to 1 in 10 people). The signs and symptoms of liver problems include:
 - nausea (feeling sick)
 - vomiting (being sick)
 - stomach pain
 - muscle aches and pains
 - fever
 - skin or whites of your eyes turn yellow
 - being more tired than usual
 - feeling like you have the flu

Tell your doctor immediately if you have any of these symptoms as your doctor may decide to stop the treatment.

The following other side effects have also occurred:

Very common (may affect more than 1 in 10 people):

- diarrhoea
- nausea and vomiting (feeling or being sick)
- stomach pain, discomfort or stomach bloating
- decreased appetite
- indigestion

- flatulence (wind)
- constipation
- weight loss

Common (may affect up to 1 in 10 people):

- inflammation of the stomach and intestine that causes diarrhoea and vomiting
- regurgitation (bringing food back up)
- burping
- feeling of incomplete defaecation (bowel movement), urgent need to defaecate
- bleeding from your rectum (back passage) or blood in your stool
- dizziness, headache, migraine
- tiredness, lack of energy or general weakness
- enlarged, damaged or fatty liver
- purple discoloration of the skin, solid bumps on the skin, rash, yellow bumps on the skin
- changes to blood clotting tests
- changes to blood cell count
- decrease in levels of potassium, carotene, vitamin E, vitamin K in your blood
- muscle spasms

Uncommon (may affect up to 1 in 100 people):

- flu or cold, fever, inflammation of your sinuses, cough
- low red blood cell count (anaemia)
- dehydration, dry mouth
- increased appetite
- burning or prickling of the skin
- swelling of the eye
- ulcer or sore spot in the throat
- vomiting blood
- dry skin
- blister
- excessive sweating
- joint pain or swelling, pain in hands or feet
- muscle pain
- blood or protein in the urine
- chest pain
- changes to your walking (gait)
- abnormal lung function test

Not known (frequency cannot be estimated from the available data)

- hair loss (alopecia)
- muscle pain (myalgia)
- loss of fluid that may cause headache, dry mouth, dizziness, tiredness or unconsciousness (dehydration)

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via: Yellow Card Scheme
 Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store

By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Lojuxta

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the label or carton after “EXP”. The expiry date refers to the last day of that month.

Store below 30°C.

Keep the bottle tightly closed in order to protect from moisture.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6. Contents of the pack and other information

What Lojuxta contains

- The active substance is lomitapide.
Lojuxta 5 mg: each hard capsule contains lomitapide mesylate equivalent to 5 mg lomitapide.
Lojuxta 10 mg: each hard capsule contains lomitapide mesylate equivalent to 10 mg lomitapide.
Lojuxta 20 mg: each hard capsule contains lomitapide mesylate equivalent to 20 mg lomitapide.
- The other ingredients are: pregelatinized starch, sodium starch glycolate (Type A), microcrystalline cellulose, lactose monohydrate, silica colloidal anhydrous and magnesium stearate (for information on lactose monohydrate, see section 2 under ‘Lojuxta contains lactose’).

Capsule shell:

- The capsule shell for the 5 mg and 10 mg capsules contains gelatin, titanium dioxide (E171) and red iron oxide (E172).
- The capsule shell for the 20 mg capsule contains gelatin and titanium dioxide (E171).
- All capsules have edible black ink for printing.

What Lojuxta looks like and contents of the pack

- Lojuxta 5 mg is an orange cap/orange body hard capsule with “5 mg” printed on the body and “A733” printed on the cap in black ink.
- Lojuxta 10 mg is an orange cap/white body hard capsule with “10 mg” printed on the body and “A733” printed on the cap in black ink.
- Lojuxta 20 mg is a white cap/white body hard capsule with “20 mg” printed on the body and “A733” printed on the cap in black ink.

Pack sizes are:

28 capsules.

Marketing Authorisation Holder

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Other sources of information

This medicine has been authorised under ‘exceptional circumstances’. This means that because of the rarity of this disease it has been impossible to get complete information on this medicine. The Medicines and Healthcare products Regulatory Agency will review any new information on this medicine every year and this leaflet will be updated as necessary.

Detailed information on this medicine is available on the Medicines and Healthcare products Regulatory Agency web site:<http://www.mhra.gov.uk>