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Patient leaflet in accordance with the Pharmacists' Regulations (Preparations) – 1986

This medicine is dispensed with a doctor's prescription only

Lojuxta 5 mg Lojuxta 10 mg Lojuxta 20 mg

Hard capsules

Active ingredient:

Each hard capsule of Lojuxta 5 mg contains lomitapide (as mesilate) 5 mg

Each hard capsule of Lojuxta 10 mg contains lomitapide (as mesilate) 10 mg

Each hard capsule of Lojuxta 20 mg contains lomitapide (as mesilate) 20 mg

Inactive ingredients and allergens in this medicine: See section 6 'Additional information' and section 2: 'Important information about some of this medicine's ingredients'.

Read the entire leaflet carefully before you start using this medicine.

This leaflet contains concise information about this medicine. If you have any further questions, consult your doctor or pharmacist.

This medicine has been prescribed to treat your illness. Do not pass it on to others. It may harm them, even if it seems to you that their illness is similar to yours.

1. What is this medicine intended for?

Lojuxta is used with a low-fat diet and other lipid lowering treatments, including LDL apheresis in patients with homozygous familial hypercholesterolaemia (HoFH) to lower:

LDL cholesterol ("bad" cholesterol)

total cholesterol (TC)

apolipoprotein-B

non-HDL cholesterol

Therapeutic group:

Lipid-modifying agents.

Lojuxta contains the active ingredient called lomitapide 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 in the blood.

2. Before using this medicine

Do not use this medicine if:

- You are sensitive (allergic) to the active ingredient (lomitapide) or to any of the other ingredients this medicine contains (see section 6 - 'Additional information')
- You have liver problems or unexplained abnormal liver tests
- You have bowel problems or cannot absorb food from your bowel
- You take more than 40 mg of simvastatin daily (another medicine used to lower cholesterol)
- 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, ritonavir (for HIV infection)

- diltiazem, verapamil (for high blood pressure or angina), dronedarone (to regulate heart rhythm)
- You are pregnant, trying to get pregnant, or think you may be pregnant (see section 2 'Pregnancy and breast-feeding')

Special warnings about using this medicine

Before treatment with Lojuxta, tell your doctor if:

- 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 refer you for 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:

There is no information about the safety of use and effectiveness of this medicine in children and adolescents under the age of 18. Therefore, the use in children and adolescents is not recommended.

Tests and follow-up:

Blood tests should be taken before starting treatment with Lojuxta, when your dose is increased, and regularly during treatment. These blood tests help your doctor adjust your dose. If your tests show signs of liver problems, your doctor may decide to reduce your dose or stop the treatment.

Drug interactions

If you are taking or have recently taken other medicines, including nonprescription medications and dietary supplements, tell your doctor or pharmacist.

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, 'Do not use this medicine if')
- Some medicines for high blood pressure, angina or to regulate heart rhythm (see section 2 'Do not use this medicine if')

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

- medicines which lower cholesterol (e.g. atorvastatin)
- 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 (such as 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 ‘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 pains (myalgia) or weakness (myopathy) may also occur. **Contact your doctor immediately if you experience any unexplained muscle pains, tenderness or weakness.** You should not take more than 40 mg of simvastatin when using Lojuxta (see section 2: ‘Do not take this medicine if’)
- 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 for the treatment of 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 and 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)
- antihistamine medicines to treat hay fever (e.g. fexofenadine)

• Do not use this medicine if you are taking CYP3A4 inhibitors (medicines to treat bacterial, fungal or viral infections and medicines to treat depression, high blood pressure or angina).

Using the medicine with food and drink

- Do not drink any type of grapefruit juice.
- 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. Consult a dietitian to learn what you can eat while taking Lojuxta.

Using this medicine and alcohol consumption

- The use of alcohol during Lojuxta treatment is not recommended.

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 recommended by your doctor. If you use contraceptive pills and suffer from 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 passes 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

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

Important information about some of this medicine's ingredients

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.

This medicine contains less than 1 mmol sodium (23 mg) per capsule, that is to say essentially 'sodium-free'.

3. How to use this medicine?

- Always use this medicine according to your doctor's instructions. Check with your doctor or pharmacist if you are not sure about your dose or about how to take this medicine. This medicine should be given to you by a doctor experienced in the treatment of blood lipid disorders who will also monitor you regularly.
- Only your doctor will determine your dose and how you should take this medicine. The recommended starting dose is a 5 mg capsule, once a day. Your doctor may increase your dose gradually over time, up to a maximum of 60 mg, once a 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.

Do not exceed the recommended dose.

Form of administration

- Take this medicine once a day at bedtime with a glass of water at least 2 hours after your evening meal (see section 2 'Using the medicine with food and drink').
- Do not take this medicine with food, as taking these capsules with food can cause stomach problems.
- Take the capsule whole. Do not open, crush, dissolve or chew the capsule before swallowing it.

- If you take another medicine that lowers cholesterol by binding bile acids, such as colestevlam or cholestyramine, take it 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 appears below. Ask your doctor or dietitian how to obtain these supplements. See section 2 'Using the medicine with food and drink'.

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 have accidentally taken a higher dose

- Contact your doctor or pharmacist immediately.
- If you have taken an overdose, or if a child has accidentally swallowed some medicine, immediately see a doctor or go to a hospital emergency room and bring the medicine package with you.

If you forget to take the medicine

- 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 this medicine

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

Adhere to the treatment as recommended by your doctor. Even if your health improves, do not stop taking this medicine without consulting your doctor.

Do not take medicines in the dark! Check the label and dose every time you take medicine. Wear glasses if you need them.

If you have any further questions about using this medicine, consult your doctor or pharmacist.

4. Side effects

Like with all medicines, using Lojuxta may cause side effects in some users. Do not be alarmed by this list of side effects. You may not experience any of 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
 - vomiting
 - stomach pain

- muscle aches
- fever
- skin or whites of your eyes turn yellow
- being more tired than usual
- feeling like you have the flu

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

Additional side effects

Very common side effects (may appear in more than 1 in 10 people):

- diarrhoea
- nausea and vomiting
- stomach pain, discomfort or stomach bloating
- decreased appetite
- indigestion
- flatulence (wind)
- constipation
- weight loss

Common side effects (may appear in 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 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 side effects (may appear in 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
- blisters
- 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

Side effects of unknown frequency (frequency cannot be estimated from the available information):

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

If you experience any side effect, if any side effect gets worse, or if you experience a side effect not mentioned in this leaflet, consult your doctor.

You can report side effects to the Ministry of Health by following the link 'Reporting Side Effects of Drug Treatment' on the Ministry of Health home page (www.health.gov.il) which links to an online form for reporting side effects. You can also use this link: <https://sideeffects.health.gov.il>

5. How to store the medicine?

- Prevent poisoning! To prevent poisoning, keep this, and all other medicines, in a closed place, out of the reach and sight of children and/or infants. Do not induce vomiting unless explicitly instructed to do so by a doctor.
- Do not use the medicine after the expiry date (exp. date) which is stated on the package. The expiry date refers to the last day of that month.
- Storage conditions:
Store below 30°C.
Keep the bottle tightly closed to protect against humidity.
Do not throw away medicines via wastewater or household waste. Ask the pharmacist how to throw away medicines you no longer use. These measures will help protect the environment

6. Additional information

In addition to the active ingredient, this medicine also contains:
lactose monohydrate, microcrystalline cellulose, pregelatinised starch, sodium starch glycolate, silica colloidal anhydrous and magnesium stearate.

(For more information about lactose monohydrate, see Section 2 'Important information about some of this medicine's ingredients').

Capsule shell:

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

What the medicine 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" 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" 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 size: 28 hard capsules.

Registration holder’s name and address: Medison Pharma Ltd., 10 Hashiloach St., POB 7090, Petach Tikva.

Manufacturer’s name and address:

Catalent CTS, 10245 Hickman Mills Drive, Kansas City, MO 64137, USA

For:

Amryt Phatma DAC, 45 Mespil Road, Dublin 4, D04 W2F1, Ireland

This leaflet was revised in March 2024.

Registration number of the medicine in the Ministry of Health’s National Drug Registry:

Lojuxta 5 mg - 152-85-33996

Lojuxta 10 mg - 152-86-33998

Lojuxta 20 mg - 152-87-33999

Lojuxta-PIL-0324-V1