Lojuxta®
lomitapide

PRESCRIBING CHECKLIST

Adverse events should be reported. For adverse events reporting information please see back of document.

PATIENT CHECKLIST

The following topics should be discussed with the patient prior to or at the time of prescribing Lojuxta. The patient should also be encouraged to read the package leaflet (provided in each carton of Lojuxta), the Patient Care Guide and the Patient Alert card for Lojuxta for further information.

Dietary advice

- ☐ Follow a low-fat eating plan with < 20 % energy from fat.
- ☐ Take vitamin E and essential fatty acids daily.
- ☐ Avoid alcohol and grapefruit juice.
- ☐ Lojuxta should be taken on an empty stomach, at least 2 hours after the evening meal.

Pregnancy advice

- [ ] Use effective contraception.
- [ ] Advise there may be a loss of effectiveness of oral contraceptives due to diarrhoea or vomiting. In cases of protracted or severe diarrhoea and/or vomiting lasting more than 2 days, additional contraception should be used until 7 days after resolution of symptoms.
- [ ] Tell their doctor immediately if they suspect they might be pregnant.

Medical follow-up

- [ ] Attend for liver monitoring tests.
- [ ] Report any suspected adverse events.

PHYSICIAN CHECK LIST

The following activities should be performed prior to prescribing Lojuxta and during on-going treatment to support the safe use of the product.
Further information is provided in the Summary of Product Characteristics and the Healthcare Professional Guide.

Patient materials

- ☐ Patient Care Guide and the Patient Alert Card for Lojuxta given to the patient with explanation. The patient should carry the Patient Alert Card for Lojuxta with him/her at all times while taking Lojuxta.

Liver monitoring

- ☐ Measure ALT, AST, bilirubin, alkaline phosphatase, serum albumin and gamma GT at baseline.
- ☐ Measure ALT and AST (at a minimum) monthly or prior to each dose increase for the 1st year and thereafter 3 monthly.
- ☐ Perform screening and monitoring for evidence of steatohepatitis/fibrosis at baseline and annually, in consultation with a hepatologist.

Patient selection

- [ ] Confirm patient is diagnosed with HoFH and aged 18 years and above.
- [ ] Check for contraindications including pregnancy.

Drug interactions

- [ ] Check for drug interactions with CYP3A4 inhibitors, CYP3A4 inducers, p-glycoprotein substrates, coumarin anticoagulants, statins.
- [ ] Report any suspected adverse events.

Refer to Prescribing Checklist overleaf for adverse event reporting information.

REPORTING ADVERSE EVENTS

Healthcare professionals are asked to report any suspected adverse reactions.
Adverse events can be reported to the Ministry of Health using the online form for adverse event reporting which can be found on the Ministry of Health website: www.health.gov.il or by using the following link: https://sideeffects.health.gov.il/.
Adverse events can be also reported to Medison Pharma Ltd. by email: PVIsrael@medisonpharma.com.

This guide was reviewed and approved by the Ministry of Health in Jan-2025.

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