Lojuxta® lomitapide

LIVER MONITORING RECOMMENDATIONS DURING TREATMENT WITH LOJUXTA CAPSULES

Adverse events should be reported.
Adverse event reporting information can be found at the back of this document.

LIVER MONITORING RECOMMENDATIONS

There is a risk of hepatotoxicity with Lojuxta. It is important to monitor the liver on a regular basis.

Regular screening for liver transaminases

Lojuxta can cause elevations in alanine aminotransferase (ALT) and aspartate aminotransferase (AST). It is important to perform the following liver-related tests:

Prior to initiating treatment	Measure ALT, AST, alkaline phosphatase, total bilirubin, Gamma GT and serum albumin.
During the 1st year	Prior to each dose escalation of Lojuxta or monthly, whichever occurs first: measure ALT, AST (at a minimum).
After the 1st year	At least every 3 months and before any increase in dose: measure ALT, AST (at a minimum).

If aminotransferase elevations are accompanied by clinical symptoms of liver injury (such as nausea, vomiting, abdominal pain, fever, jaundice, lethargy, flu-like symptoms), increases in bilirubin ≥2x ULN, or active liver disease, discontinue treatment with Lojuxta and refer the patient to a hepatologist for further investigation.

Reintroduction of treatment may be considered if the benefits are considered to outweigh the risks associated with potential liver disease.

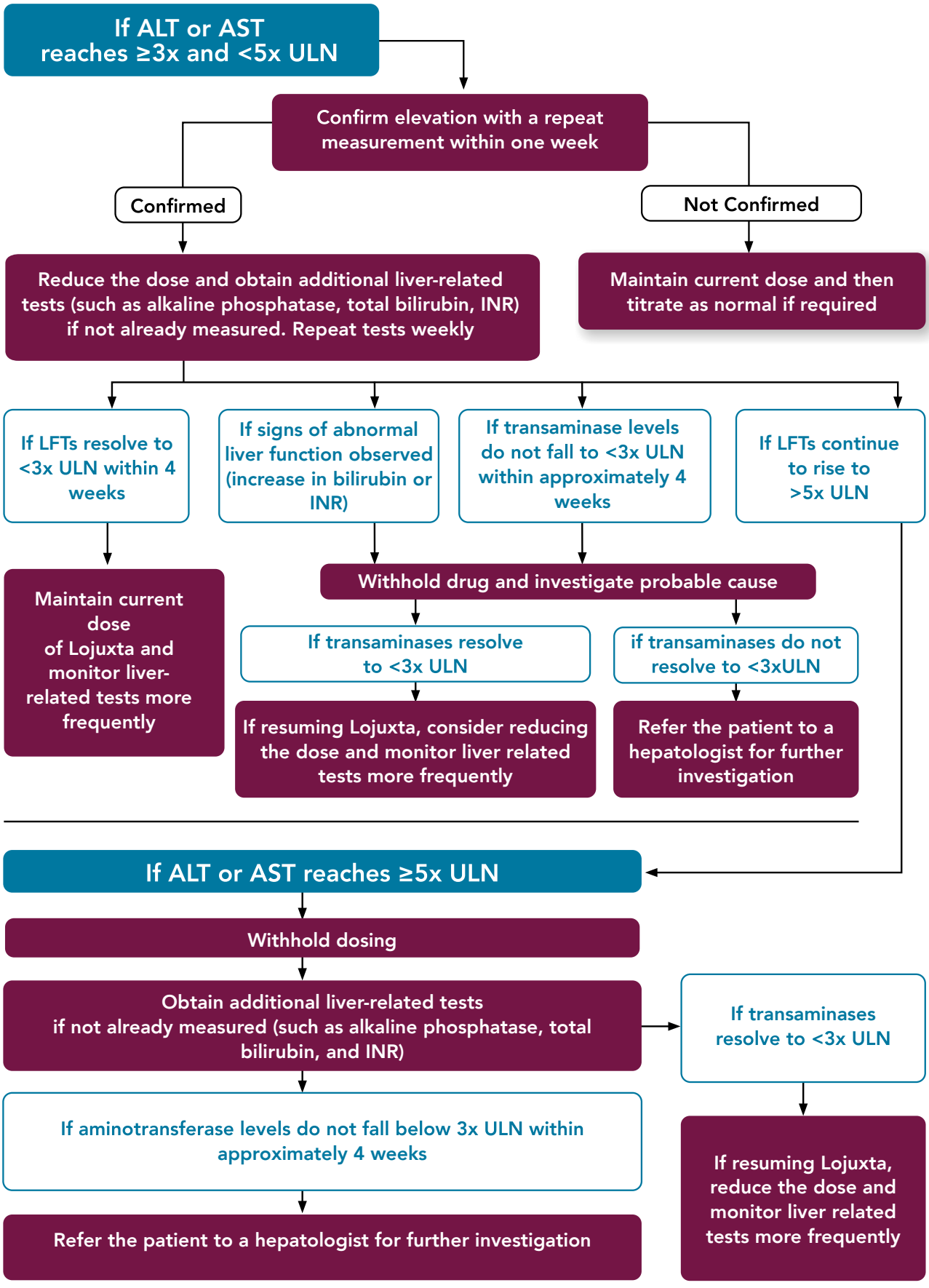
Dosing adjustments are required for patients who develop transaminases values ≥3x the upper limit of normal (ULN)* during treatment per the recommendations on the adjacent page.

Regular screening for steatohepatitis/fibrosis should be performed at baseline and on an annual basis as follows:

1	Imaging for tissue elasticity, e.g. Fibroscan, acoustic radiation force impulse (ARFI), or magnetic resonance (MR) elastography.
2	Gamma-GT and serum albumin to detect possible liver injury.
3	Measurement of biomarkers and/or scoring methods. This should include at least one marker in each of the following categories: • High sensitivity C-reactive protein (hs-CRP), erythrocyte sedimentation rate (ESR), CK-18 Fragment, NashTest (liver inflammation); • Enhanced Liver Fibrosis (ELF) panel, Fibrometer, AST/ALT ratio, Fib-4 score, Fibrotest (liver fibrosis).

The performance of these tests and their interpretation should involve collaboration between the treating physician and the hepatologist. Patients with results suggesting the presence of steatohepatitis or fibrosis should be considered for liver biopsy. If a patient has biopsy-proven steatohepatitis or fibrosis, the benefit- risk should be reassessed and treatment stopped if necessary.

Lojuxta dosing adjustments for patients who develop transaminase values ≥ 3x upper limit of normal (ULN) during treatment.



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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