Generic Name:
Obeticholic acid
Trade Name:
Ocaliva
Company:
Intercept Pharmaceuticals
Notes:

FDA warned that obeticholic acid has been incorrectly dosed daily instead of weekly in patients with moderate to severe primary biliary cholangitis (or PBC), a rare chronic liver disease, increasing the risk of serious liver injury.

To ensure correct dosing and reduce the risk of liver problems, the agency is clarifying the current recommendations for screening, dosing, monitoring, and managing patients with PBC with moderate to severe liver disease who are taking obeticholic acid. FDA is adding a new boxed warning to highlight this information in the prescribing information of the drug label and are also requiring a Medication Guide for patients to inform them about this issue.

Obeticholic acid works by increasing bile flow from the liver, suppressing bile acid production in the liver, and reducing exposure of the liver to toxic levels of bile acids. Progressive PBC can lead to liver failure or death. Treatment of PBC with obeticholic acid may delay or prevent disease progression.

Health professionals should follow the obeticholic acid dosing regimen in the drug label, which is based on calculating a Child-Pugh score in PBC patients with suspected liver cirrhosis before treatment to determine their specific classification and starting dosage. Close monitoring is recommended for patients at an increased risk of liver decompensation.

Educate patients and caregivers about the symptoms of worsening liver function. Temporarily stop obeticholic acid in patients with laboratory or clinical evidence of worsening liver function that may indicate decompensation and monitor the patient?s liver function. If a patient?s condition returns to baseline, weigh the risks and benefits of restarting obeticholic acid. Reinitiate using the recommended starting dosage based on Child-Pugh classification.

As a condition of approval, FDA required the obeticholic acid manufacturer, Intercept Pharmaceuticals, to continue studying the medication in patients with advanced PBC. FDA expects to receive results from these clinical trials in 2023.

FDA said it will continue to monitor this medication and update the public if new information becomes available.

Medication Monitor Categories:
Alerts and Recalls