Indian Health Service
National Pharmacy and Therapeutics Committee

Pharmacovigilance Drug Safety Communication

FDA restricts use of obeticholic acid (Ocaliva®) in primary biliary cholangitis (PBC) patients with advanced cirrhosis

Obeticholic acid (Ocaliva®) is used to treat a rare, chronic liver disease known as primary biliary cholangitis (PCB). The FDA issued a Drug Safety Communication restricting the use of obeticholic acid (Ocaliva®) in patients having PBC who also have advanced cirrhosis of the liver. The FDA identified 25 PBC patients with cirrhosis who took obeticholic acid, especially those with evidence of advanced cirrhosis, who developed liver failure, sometimes requiring liver transplant. The FDA has added advanced cirrhosis as a contraindication in the prescribing information and updated the Boxed Warning. The FDA believes the benefits of obeticholic acid outweigh the risks for PBC patients who do not have advanced cirrhosis.

Recommendations for Patients: Talk to your health care professional about the new warnings.

Contact your prescriber immediately if you develop any of the following symptoms:

- Swollen belly
- Yellow eyes or skin
- Bloody or black stools
- Coughing up or vomiting blood
- Mental status changes

Contact your provider if these symptoms are severe or do not go away after a few days:

- Belly pain
- Nausea, vomiting, or diarrhea
- Loss of appetite or weight loss
- New or worsening tiredness
- Weakness
- Fever and chills
- Lightheadedness
- Less frequent urination

Recommendations for health care professionals:

- Determine and routinely monitor the patient for advanced cirrhosis (defined as cirrhosis with current or prior evidence of hepatic decompensation [e.g., encephalopathy, coagulopathy] or portal hypertension [e.g., ascites, gastroesophageal varices, persistent thrombocytopenia]) and clinically significant liver-related adverse reactions (acute-on-chronic liver disease with nausea, vomiting, diarrhea, jaundice, scleral icterus, and/or dark urine).
- Permanently discontinue obeticholic acid in patients with advanced cirrhosis or symptoms of clinically significant liver-related adverse reactions.

The complete Drug Safety Communication can be viewed on the FDA website.

To help the FDA track safety issues with obeticholic acid and other medications, please report adverse events to the MedWatch program as recommended in the Indian Health Manual. Instructions for reporting can be found online at the NPTC Pharmacovigilance website.

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