Consumer Update Dec 2021

Obeticholic acid-risks of hepatic decompensation and liver failure

EDA performs Label Update to include the following:

Warnings and Precautions

Hepatic Decompensation and Failure in PBC Patients with Cirrhosis

Use in Specific Populations

Hepatic Impairment

Hepatic decompensation and failure, sometimes fatal or resulting in liver transplant, have been reported with treatment in PBC patients with cirrhosis, either compensated or decompensated . **Obeticholic acid** is contra-indicated in patients with decompensated cirrhosis (e.g., Child-Pugh Class B or C), in those with a prior de-compensation event, or with compensated cirrhosis who have evidence of portal hypertension (e.g., ascites, gastroesophageal varices, persistent thrombocytopenia)

In PBC clinical trials, a dose-response relationship was observed for the occurrence of hepatic adverse reac-tions

Plasma exposure to obeticholic acid and its active conjugates, increases significantly in patients with moder-ate to severe hepatic impairment .

Routinely monitor patients for progression of PBC with laboratory and clinical assessments. Closely monitor patients with compensated cirrhosis, concomitant hepatic disease, and/or severe intercurrent illness for new evidence of portal hypertension (e.g., ascites, gastroesophageal varices, persistent thrombocytopenia) or in-creases above the upper limit of normal in total bilirubin, direct bilirubin, or prothrombin time to determine whether drug discontinuation is needed. Permanently discontinue OCALIVA in patients who develop labor-atory or clinical evidence of hepatic decompensation, have compensated cirrhosis and develop evidence of portal hypertension, or experience clinically significant hepatic adverse reactions while on treatment. Inter-rupt treatment during severe inter current illness

References: *FDA (Click here)*