Direct Healthcare Professional Communication

Jan 2025

Obeticholic acid: Risk of Serious liver injury may be observed in patients without cirrhosis treated with obeticholic acid

Dear Healthcare Professional,

The General Administration for Pharmaceutical Vigilance (PVGA) at the Egyptian drug authority (EDA) would like to inform you **about important safety information related to Medicines containing obeticholic concerning risk of Serious liver injury.**

Summary

- Risk of serious liver injury may be observed among patients being treated for primary biliary cholangitis (PBC) with (obeticholic acid) who did not have cirrhosis of the liver.
- The use of obeticholic acid in patients who have PBC with advanced cirrhosis of the liver can cause serious harm in those patients.
- Treatment with obeticholic acid should not be started if the patient has decompensated cirrhosis or a history of a decompensation event prior to treatment initiation.
- Health care professionals should monitor liver tests frequently in patients being treated with obeticholic acid to detect and address worsening liver function early.
- HCPs should discontinue obeticholic acid treatment with any evidence of liver disease progression or if efficacy is not established.
- HCPs should explain the signs and symptoms of worsening liver injury to patients receiving obeticholic acid and direct them to contact you immediately if they develop any signs or symptoms of worsening liver injury.

Background on the safety concern

Obeticholic acid is a semi-synthetic bile acid that works by activating the farnesoid X receptor (FXR), which controls the production of bile. By activating this receptor, Obeticholic acid is expected to reduce the production of bile in the liver, thus reducing the exposure of the liver to toxic levels of bile acids.

obeticholic acid is authorized for the treatment of patients with primary biliary cholangitis (also known as primary biliary cirrhosis). obeticholic acid is to be used in combination with another medicine, ursodeoxycholic acid (UDCA), in patients who have not responded adequately to UDCA, or on its own in adults who are unable to tolerate treatment with UDCA.

Primary biliary cholangitis is a rare and life-threatening disease that causes the gradual destruction of the small bile ducts in the liver. These ducts transport fluid called bile from the liver towards the intestines where it is used to help digest fats. As a result of the destruction of the ducts, bile builds up in the liver causing damage. As the disease progresses, it leads to liver cirrhosis (scarring of the liver) and liver failure, and may increase the risk of liver cancer.

There are limited treatments available for patients with primary biliary cholangitis. Liver transplantation can significantly improve a patient's chance of survival; however this is a long and complex operation only suitable for patients who have advanced liver disease.

Reference

EMA: https://www.ema.europa.eu/en/news/new-medicine-rare-chronic-liver-disease

FDA:https://www.fda.gov/drugs/drug-safety-and-availability/serious-liver-injury-being-observed-patients-without-cirrhosis-taking-ocaliva-obeticholic-acid-treat

Call for reporting

Healthcare professionals are asked to report any suspected adverse reactions via the Egyptian reporting system:

Name: General Administration for Pharmaceutical Vigilance

Email: pv.followup@edaegypt.gov.eg

Online reporting: https://vigiflow-eforms.who-umc.org/eg/med
QR Code:

PO Box: 11451

Hotline: 15301