Direct Healthcare Professional Communication

March 2022

Important communication regarding Obeticholic acid

Dear Healthcare professional,

The Egyptian Pharmaceutical Vigilance Center of the Central Administration for Pharmaceutical Care at The Egyptian Drug Authority would like to inform you of the following:

Summary

- The indication and possibility of use of **Obeticholic acid** have been restricted for the treatment of primary biliary cholangitis (PBC) in patients without cirrhosis or with compensated cirrhosis without signs of portal hypertension.
- **Obeticholic acid** is now contraindicated in patients with
    - decompensated cirrhosis (e.g. Child-Pugh classification B or C) or patients with an early decompensation event
    - compensated cirrhosis with signs of portal hypertension (e.g. ascites, gastrovarix esophageal, persistent thrombocytopenia)
- The "Warnings and Precautions" section of **Obeticholic acid** now includes information on hepatic decompensation and liver failure, which have occasionally led to death or liver transplantation in patients with PBC treated with **Obeticholic acid** and presenting with compensated or decompensated cirrhosis.
- The "Dosage/Application" section of **Obeticholic acid** has been modified. Dosing indications for patients with Child-Pugh classification B or C or patients with a previous decompensation event have been removed as **Obeticholic acid** is now contraindicated in these patients.
- In the professional information of **Obeticholic acid**, additional changes have been made based on these safety instructions and also with regard to the application of **Obeticholic acid** in patients with concomitant liver disease as well as severe intercurrent illness.

General informations

The purpose of this letter is to inform you of important new safety information regarding Obeticholic acid, authorized for the treatment of primary biliary cholangitis (PBC) in combination with ursodeoxycholic acid (UDCA) in adults not responding sufficiently to UDCA or as monotherapy in adults intolerant to UDCA.

Changes to the Obeticholic acid Professional Information have been made by verification of reported adverse reaction cases and from reports in the medical literature of hepatic decompensation or hepatic failure during treatment with Obeticholic acid in patients with PBC with cirrhosis. The Professional

21st Abdel-Aziz Al-Saud, Manial Al-Roda,Cairo
pv.head@edaegypt.gov.eg; pv.safety@edaegypt.gov.eg;
Tel.: 237484988 Ext.:1470

Information for Obeticholic acid has been amended and additional safety guidance including restriction of indication, newly contraindicated population and new warnings and precautions have been reinstated.

Measures and instructions/recommendations for healthcare professionals

Advise your patients about the risks and benefits of Obeticholic acid. Before starting treatment with Obeticholic acid, it is important to determine whether your patient has decompensated cirrhosis or a previous event of decompensation or compensated cirrhosis with evidence of portal hypertension, as Obeticholic acid is contraindicated in these patients.

Perform regular laboratory tests and clinical examinations to monitor your patients for the progression of PBC, including liver-related adverse events.

Monitor your patients closely if they have compensated cirrhosis, concurrent liver disease (eg, autoimmune hepatitis, alcohol-related liver disease), and/or severe intercurrent disease, to detect any new evidence of portal hypertension (eg, ascites, gastroesophageal varices, persistent thrombocytopenia < 150 x 109 /l) or increases in total bilirubin, direct bilirubin, or prothrombin time greater than normal, in order to determine if the drug should be stopped.

Interrupt Obeticholic acid treatment in patients with severe intercurrent disease or liver-related adverse events and monitor the patient's liver function. After resolution of severe intercurrent disease or clinically significant liver-associated adverse events, and provided there is no evidence of hepatic decompensation confirmed by laboratory or clinical tests, weigh the potential risks and benefits resumption of treatment with Obeticholic acid. Instruct your patients to contact you immediately in the event of any liver-related adverse event that occurs during treatment with Obeticholic acid.

You should permanently discontinue treatment with Obeticholic acid in the following patients:

• Patients with evidence of hepatic decompensation confirmed by laboratory or clinical tests (eg, ascites, jaundice, variceal hemorrhage, hepatic encephalopathy, Child-Pugh classification B or C),

• Patients with compensated cirrhosis who develop signs of portal hypertension (eg, ascites, esophageal varices, persistent thrombocytopenia < 150 x 109 /l

• Patients who experienced clinically significant hepatic side effects during treatment,

• Patients who develop total biliary occlusion.

References

https://www.swissmedic.ch/swissmedic/fr/home/medicaments-a-usage-humain/surveillance-du-marche/health-professional-communication--hpc-/dhpc-ocaliva-obeticholsaeure.html

Call for reporting

21st Abdel-Aziz Al-Saud, Manial Al-Roda,Cairo
pv.head@edaegypt.gov.eg; pv.safety@edaegypt.gov.eg;
Tel.: 237484988 Ext.:1470

The Egyptian Pharmaceutical Vigilance Center is reminding HCP and public to report any safety information regarding human medicinal products including adverse drug reactions, medications errors, lack of efficacy and other medicine related problems through the following contacts:

The Egyptian Pharmaceutical Vigilance Center

Address: 21 Abd El Aziz Al Soud Street, El-Manial, Cairo, Egypt, And PO Box: 11451
Telephone: (+2)02 25354100, Extension: 1470 Fax: +202 – 23610497

Hotline: 15301

Email: Pv.follow-up@edaegypt.gov.eg

Online reporting: https://primaryreporting.who-umc.org/EG
QR Code:

21st Abdel-Aziz Al-Saud, Manial Al-Roda,Cairo
pv.head@edaegypt.gov.eg; pv.safety@edaegypt.gov.eg;
Tel.: 237484988 Ext.:1470