COMMUNICATION

COM-2024-082

13 DECEMBER 2024

URGENT PLEASE REVIEW

Safety Notification

PharmPix Clinical Department

PharmPix is committed to the health and wellness of our members.

The clinical team wants to communicate you with the latest up-to-date drug safety information.

U.S. Food & Drug Administration Publication Date:

12/12/2024

Drug Indication:

Ocaliva® is indicated for the treatment of adult patients with primary biliary cholangitis (PBC) without cirrhosis or with compensated cirrhosis who do not have evidence of portal hypertension. Ocaliva® can be used either in combination with ursodeoxycholic acid (UDCA) in patients that have an inadequate response to UDCA or as monotherapy in patients unable to tolerate UDCA.

Safety Topic:

Serious liver injury being observed in patients without cirrhosis taking Ocaliva® (obeticholic acid) to treat primary biliary cholangitis.

Serious Liver Injury being Observed in Patients Taking Ocaliva® (obeticholic acid)

It is for this reason that we are notifying you that on 12/12/2024 the US Food and Drug Administration (FDA) published a safety communication for the following product: Ocaliva® (obeticholic acid).

Reason for Communication:

The FDA has reviewed post market clinical trial data and identified cases of serious liver injury among patients being treated for primary biliary cholangitis (PBC) with Ocaliva® (obeticholic acid) who did not have cirrhosis of the liver. The agency will continue to monitor the medication's safety and provide updates if additional information becomes available.

Pharmacy Required Action:

Advise patients about this safety risk, as well as the potential benefits and risks of continuing or discontinuing treatment with Ocaliva®. Encourage them to discuss any concerns, including possible alternative treatments. Health care professionals should monitor liver tests frequently in patients being treated with Ocaliva® to detect and address worsening liver function early. Patients should contact their health care provider immediately if they experience symptoms that could indicate worsening liver injury, such as abdominal pain, yellow eyes or skin, bloody or black stools, and nausea, vomiting or diarrhea.

Assess whether the potential benefits of continuing the drug outweigh the potential risks highlighted in this safety communication.

Remember you can report adverse events related to this or any other drug product at MedWatch: The FDA Safety Information and Adverse Event Reporting Program by any of the following ways:

Complete and submit the MedWatch Online Voluntary Reporting Form online.

Download FDA Form 3500 or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form or submit by fax to 1-800-FDA-0178.

Additional information can be found at: MedWatch: The FDA Safety Information and Adverse Event Reporting Program.

If you have any questions or wish to have more information regarding this document, you can call us at 787-522-5252- ext. 219. Our pharmacists will help you.

In addition, know that you can access our recent communications at our providers' portal: https://www.pharmpix.com/providers/.

PharmPix Drug Safety Communication Number COM-2024-082 December 2024

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REFERENCES:

1. U.S. Food and Drug Administration. (2024, December 13). *Serious liver injury being observed in patients without cirrhosis taking Ocaliva (obeticholic acid) to treat primary biliary cholangitis*. https://www.fda.gov/drugs/drug-safety-and-availability/serious-liver-injury-being-observed-patients-without-cirrhosis-taking-ocaliva-obeticholic-acid-treat

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