

## Ocaliva<sup>®</sup> (obeticholic acid) – Safety Communication

- On September 21, 2017, the [FDA announced](#) that [Ocaliva \(obeticholic acid\)](#) is being incorrectly dosed in some patients with moderate to severe decreases in liver function, resulting in an increased risk of serious liver injury and death.
  - Patients are receiving excessive dosing, particularly a higher frequency of dosing than is recommended in the drug label.
  - Ocaliva may also be associated with liver injury in some patients with mild disease who are receiving the correct dose.
- Ocaliva is indicated for the treatment of primary biliary cholangitis (PBC) in combination with [ursodeoxycholic acid \(UDCA\)](#) in adults with an inadequate response to UDCA, or as monotherapy in adults unable to tolerate UDCA.
- PBC causes the bile ducts in the liver to become inflamed, damaged and destroyed. This causes bile, a fluid that helps in digestion, to build up in the liver. This build-up damages the liver over time, eventually causing it to lose its ability to function.
- The FDA recommends:
  - Patient's baseline liver function should be determined prior to starting Ocaliva.
  - Patients with moderate to severe liver impairment (Child-Pugh B and C) should be started on the approved dosing schedule of Ocaliva 5 mg once weekly, rather than the 5 mg daily dosing used for other PBC patients, and if needed, can be increased up to a maximum approved dose of 10 mg twice weekly.
  - Healthcare professionals should monitor frequently for liver injury, and reduce the dosing frequency to once- or twice-weekly for patients who progress to moderate or severe liver impairment.
  - All patients treated with Ocaliva should be monitored frequently for liver injury. If liver injury is suspected, Ocaliva should be discontinued. After the patient has stabilized, healthcare providers should weigh the benefits against the risks when deciding whether to re-initiate treatment.
- Patients should contact their pharmacist or healthcare provider if they have questions or concerns about taking Ocaliva, and report any symptoms that may be signs of liver injury, including new or worsening severe skin itching.
- In the 13 months after Ocaliva was approved in May 2016, the FDA has received reports of serious liver injury or death associated with Ocaliva.
  - Nineteen cases of death were identified, of which eight provided information about the patient's cause of death. The cause of death was reported to be worsening of PBC disease in seven cases, with cardiovascular disease cited in the other case. Seven of these eight cases described patients with moderate to severe decreased liver function who received Ocaliva 5 mg daily, instead of a dose no greater than 10 mg twice weekly.

- The FDA also identified 11 cases of serious liver injury with Ocaliva use. Six of the patients who had moderate or severe decreases in liver function at baseline and developed serious liver injury were receiving Ocaliva 5 mg daily, instead of a dose no greater than 10 mg twice weekly. Three of these six patients died, which were included in the 19 death cases that were identified.



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