February 2021

Ocaliva® (obeticholic acid) for the Treatment of Patients with Primary Biliary Cholangitis (PBC) and Cirrhosis

Intercept Pharmaceuticals is working with the U.S. Food and Drug Administration (FDA) to update the prescribing information for Ocaliva with new guidance for people with primary biliary cholangitis (PBC) who reach the most advanced stages of PBC.

These changes are not finalized and will be shared on our website when they are available. Until then, the prescribing information remains the same and represents the active guidance on Ocaliva treatment for patients and healthcare providers.

If you are a patient with PBC and have questions about Ocaliva treatment, please speak with your healthcare provider.

You can access the Ocaliva prescribing information, including Boxed Warning at: https://www.interceptpharma.com/ocaliva-us-prescribing-information.

IMPORTANT SAFETY INFORMATION

OCALIVA® (obeticholic acid) is a prescription medicine that treats adults with PBC in combination with ursodeoxycholic acid (UDCA) or alone if UDCA is not tolerated.

What is the most important information I should know about OCALIVA?

OCALIVA may cause serious side effects including:

Worsening of liver problems, liver failure, in some cases leading to death, have happened in people with PBC with advanced liver cirrhosis when OCALIVA was taken more often than recommended.

If you have primary biliary cholangitis (PBC) with advanced cirrhosis, you may need a lower dose of OCALIVA. Before you start OCALIVA, and during your treatment with OCALIVA, your healthcare provider will do tests to check your liver. These tests will help your healthcare provider decide how much OCALIVA you should take and how often you should take it. If you have worsening liver problems, your dose of OCALIVA may be changed, stopped for a period of time, or stopped completely by your healthcare provider.

Tell your healthcare provider right away if you have any of the following symptoms of worsening liver problems during treatment with OCALIVA:

- Swelling of your stomach area from a build-up of fluid; yellowing of your skin or the whites of your eyes; black, tarry, or bloody stools; coughing up or vomiting blood, or your vomit looks like “coffee grounds”; or mental changes (such as confusion, sleepier than usual or harder to wake up, slurred speech, mood swings, or changes in personality)

Tell your healthcare provider right away if you have any of the following symptoms during treatment with OCALIVA and **they are severe or do not go away:**

- Stomach area pain, nausea, vomiting, or diarrhea; loss of appetite or weight loss; new or worsening fatigue, weakness, fever, or chills; lightheadedness; less frequent urination

What is OCALIVA?

OCALIVA is a prescription medicine used to treat primary biliary cholangitis (PBC) in combination with ursodeoxycholic acid (UDCA) in adults who have not responded well enough to UDCA, or alone for adults who cannot tolerate UDCA. It is not known if taking OCALIVA will improve your chance of survival or improve your symptoms of PBC. There are ongoing studies to find out how OCALIVA works over a longer period of time.

Who should not take OCALIVA?

Do not take OCALIVA if you have or had a complete blockage in the bile ducts in your liver or gallbladder.

What are the possible side effects of OCALIVA?

OCALIVA may cause serious side effects including:

- See **“What is the most important information I should know about OCALIVA?”**
- **Severe Itching.** Itching (pruritus) is a common side effect and can sometimes become severe (intense itching or itching all over your body). Severe itching can cause discomfort, problems sleeping, and problems doing daily activities, and usually needs to be treated. Tell your healthcare provider if you get severe itching or if your itching gets worse.
- **Decreases in Good Cholesterol.** Decreases in HDL-C (“good cholesterol”) have been observed in patients taking OCALIVA. Your healthcare provider will check your cholesterol levels during treatment to see if you should continue taking OCALIVA.

The most common side effects of OCALIVA include: pruritus (itching of the skin), tiredness, stomach pain and discomfort, rash, joint pain, mouth and throat pain, dizziness, constipation, swelling in your hands, ankles or feet, fast or irregular heartbeat, fever, changes in how your thyroid gland works, and eczema (skin dryness, irritation, redness, crusting, or drainage).

These are not all the possible side effects associated with OCALIVA. Call your healthcare provider for medical advice about side effects.

What should I tell my healthcare provider before taking OCALIVA?

Before taking OCALIVA, tell your healthcare provider about all of your medical conditions, including if you:

- **are pregnant or plan to become pregnant.** It is not known if OCALIVA will harm your unborn baby.
- **are breastfeeding or plan to breastfeed.** It is not known if OCALIVA passes into your breastmilk. Talk with your healthcare provider about the best way to feed your baby if you take OCALIVA.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. OCALIVA can affect the way certain medicines work. Certain other medicines may affect the way OCALIVA works.

Please see **Medication Guide** and full **Prescribing Information**, including Boxed Warning, for OCALIVA 5 mg and 10 mg tablets.

Available by prescription only.

To report negative side effects of OCALIVA, please contact Intercept Pharmaceuticals, Inc. at 1-844-782-ICPT or you may report to FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.