OCALIVA®
obeticholic acid

Get Connected
Stay Connected

INDICATION

OCALIVA, a farnesoid X receptor (FXR) agonist, 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,

either in combination with ursodeoxycholic acid (UDCA) with an inadequate response to UDCA or as monotherapy in patients unable to tolerate UDCA.

This indication is approved under accelerated approval based on a reduction in alkaline phosphatase (ALP). An improvement in survival or disease-related symptoms has not been established. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.

SELECT IMPORTANT SAFETY INFORMATION

WARNING: HEPATIC DECOMPENSATION AND FAILURE IN PRIMARY BILIARY CHOLANGITIS PATIENTS WITH CIRRHOSIS

- **Hepatic decompensation and failure, sometimes fatal or resulting in liver transplant, have been reported with OCALIVA treatment in primary biliary cholangitis (PBC) patients with either compensated or decompensated cirrhosis.**
- **OCALIVA is contraindicated in PBC patients with decompensated cirrhosis, a prior decompensation event, or with compensated cirrhosis who have evidence of portal hypertension.**
- **Permanently discontinue OCALIVA in patients who develop laboratory or clinical evidence of hepatic decompensation; have compensated cirrhosis and develop evidence of portal hypertension; or experience clinically significant hepatic adverse reactions while on treatment.**

Please see additional Important Safety Information throughout and the Full Prescribing Information, including Boxed WARNING.

Get Connected~Stay Connected

1. GETTING CONNECTED

Your health care provider determined that additional therapy is needed to treat your primary biliary cholangitis (PBC).

Unless your provider has told you otherwise, keep taking ursodiol (ursodeoxycholic acid) as prescribed.

If your healthcare provider determines that treatment support with Interconnect makes sense for you, they will complete an Enrollment packet that includes your prescription.

Once you have provided your signature, you will be enrolled in Interconnect. If your packet is completed but still needs your signature, you can go to [interconnectsupport.com/eConsent] to sign the enrollment forms electronically.[a]

2. STAYING CONNECTED

Once you're enrolled in Interconnect, your Care Coordinator will be here for support. Helping you find financial support for OCALIVA, answering your questions, addressing your concerns, helping you stay on track with your prescribed treatment regimen, and providing educational resources are all ways in which your dedicated Care Coordinator can help.

3. SUPPORTING YOU WITH INTERCONNECT

Interconnect is here to help you start and stay on therapy.

Ensure you are able to access the full Interconnect Support Services program by following the steps below:

- Complete all required documentation, as stated in step 1.
- Once you are enrolled, your Care Coordinator will call you to discuss the details of your OCALIVA prescription and answer questions you may have *(this call will come from a 1-800 number)*.
- You will need to participate in the initial call to schedule your OCALIVA shipment *(this call may come from Interconnect or the specialty pharmacy).*

Your Care Coordinator will work with you to help you find financial support options for your Intercept treatment.

4. SUPPORTING YOU THROUGH COMMUNITY AND EDUCATION

Know you are not alone in the treatment process.

- **Personalized Support:** The Interconnect Care Coordinator stays connected with you and your health care provider along the way to help treatment stay on track, answer questions, and address any concerns.
- **Educational Support:** The Interconnect Care Coordinator will be here to help you get the informational resources you need, including refill reminders and answers to questions about your Intercept treatment.

a Providing an eConsent is a way to electronically complete a Patient Authorization form which allows you to receive support services from Interconnect. Your signature also gives your Care Coordinator permission to talk to you about your condition and OCALIVA.

Interconnect® SUPPORT SERVICES

PERSONALIZED SUPPORT AND RESOURCES

Interconnect is proud to offer a wide range of resources and educational content for people living with PBC:

- Educational videos
- Ongoing PBC events
- Downloadable resources

HELP WITH THE ENROLLMENT PROCESS

Health care providers can scan the QR code to visit the Interconnect Enrollment Page, where they can enroll patients living with PBC in the Interconnect Support Services program.

Care Coordinator Information

Interconnect can help patients with PBC start and stay on therapy.

Visit www.Interconnectsupport.com

OCALIVA®
obeticholic acid

Scan the QR code, or see the attached for the full Prescribing Information, including Boxed WARNING.

IMPORTANT SAFETY INFORMATION (continued)

Contraindications

OCALIVA is contraindicated in patients with:

- decompensated cirrhosis (e.g., Child-Pugh Class B or C) or a prior decompensation event.
- compensated cirrhosis who have evidence of portal hypertension (e.g., ascites, gastroesophageal varices, persistent thrombocytopenia).
- complete biliary obstruction.

Warnings and Precautions

Hepatic Decompensation and Failure in PBC Patients with Cirrhosis

Hepatic decompensation and failure, sometimes fatal or resulting in liver transplant, have been reported with OCALIVA treatment in PBC patients with cirrhosis, either compensated or decompensated. Among postmarketing cases reporting it, median time to hepatic decompensation (e.g., new onset ascites) was 4 months for patients with compensated cirrhosis; median time to a new decompensation event (e.g., hepatic encephalopathy) was 2.5 months for patients with decompensated cirrhosis. Some of these cases occurred in patients with decompensated cirrhosis when they were treated with higher than the recommended dosage for that patient population; however, cases of hepatic decompensation and failure have continued to be reported in patients with decompensated cirrhosis even when they received the recommended dosage.

IMPORTANT SAFETY INFORMATION (continued)

Warnings and Precautions (continued)

Hepatotoxicity was observed in the OCALIVA clinical trials. A dose-response relationship was observed for the occurrence of hepatic adverse reactions including jaundice, worsening ascites, and primary biliary cholangitis flare with dosages of OCALIVA of 10 mg once daily to 50 mg once daily (up to 5-times the highest recommended dosage), as early as one month after starting treatment with OCALIVA in two 3-month, placebo-controlled clinical trials in patients with primarily early stage PBC.

Routinely monitor patients for progression of PBC, including hepatic adverse reactions, with laboratory and clinical assessments to determine whether drug discontinuation is needed. Closely monitor patients with compensated cirrhosis, concomitant hepatic disease (e.g., autoimmune hepatitis, alcoholic liver disease), and/or with severe intercurrent illness for new evidence of portal hypertension (e.g., ascites, gastroesophageal varices, persistent thrombocytopenia) or increases above the upper limit of normal in total bilirubin, direct bilirubin, or prothrombin time to determine whether drug discontinuation is needed. Permanently discontinue OCALIVA in patients who develop laboratory or clinical evidence of hepatic decompensation (e.g., ascites, jaundice, variceal bleeding, hepatic encephalopathy), have compensated cirrhosis and develop evidence of portal hypertension (e.g., ascites, gastroesophageal varices, persistent thrombocytopenia), experience clinically significant hepatic adverse reactions, or develop complete biliary obstruction. If severe intercurrent illness occurs, interrupt treatment with OCALIVA and monitor the patient's liver function. After resolution of the intercurrent illness, consider the potential risks and benefits of restarting OCALIVA treatment.

Severe Pruritus

Severe pruritus was reported in 23% of patients in the OCALIVA 10 mg arm, 19% of patients in the OCALIVA titration arm, and 7% of patients in the placebo arm in a 12-month double-blind randomized controlled clinical trial of 216 patients. Severe pruritus was defined as intense or widespread itching, interfering with activities of daily living, or causing severe sleep disturbance, or intolerable discomfort, and typically requiring medical interventions. Consider clinical evaluation of patients with new onset or worsening severe pruritus. Management strategies include the addition of bile acid binding resins or antihistamines, OCALIVA dosage reduction, and/or temporary interruption of OCALIVA dosing.

Reduction in HDL-C

Patients with PBC generally exhibit hyperlipidemia characterized by a significant elevation in total cholesterol primarily due to increased levels of high-density lipoprotein-cholesterol (HDL-C). Dose-dependent reductions from baseline in mean HDL-C levels were observed at 2 weeks in OCALIVA-treated patients, 20% and 9% in the 10 mg and titration arms, respectively, compared to 2% in the placebo arm. Monitor patients for changes in serum lipid levels during treatment. For patients who do not respond to OCALIVA after 1 year at the highest recommended dosage that can be tolerated (maximum of 10 mg once daily), and who experience a reduction in HDL-C, weigh the potential risks against the benefits of continuing treatment.

Adverse Reactions

The most common adverse reactions (≥5%) are: pruritus, fatigue, abdominal pain and discomfort, rash, oropharyngeal pain, dizziness, constipation, arthralgia, thyroid function abnormality, and eczema.

Drug Interactions

- **Bile Acid Binding Resins**
  Bile acid binding resins such as cholestyramine, colestipol, or colesevelam adsorb and reduce bile acid absorption and may reduce the absorption, systemic exposure, and efficacy of OCALIVA. If taking a bile acid binding resin, take OCALIVA at least 4 hours before or 4 hours after taking the bile acid binding resin, or at as great an interval as possible.
- **Warfarin**
  The International Normalized Ratio (INR) decreased following coadministration of warfarin and OCALIVA. Monitor INR and adjust the dose of warfarin, as needed, to maintain the target INR range when co-administering OCALIVA and warfarin.
- **CYP1A2 Substrates with Narrow Therapeutic Index**
  Obeticholic acid may increase the exposure to concomitant drugs that are CYP1A2 substrates. Therapeutic monitoring of CYP1A2 substrates with a narrow therapeutic index (e.g., theophylline and tizanidine) is recommended when co-administered with OCALIVA.
- **Inhibitors of Bile Salt Efflux Pump**
  Avoid concomitant use of inhibitors of the bile salt efflux pump (BSEP) such as cyclosporine. Concomitant medications that inhibit canalicular membrane bile acid transporters such as the BSEP may exacerbate accumulation of conjugated bile salts including taurine conjugate of obeticholic acid in the liver and result in clinical symptoms. If concomitant use is deemed necessary, monitor serum transaminases and bilirubin.

Please see accompanying Full Prescribing Information, including Boxed WARNING.

To report SUSPECTED ADVERSE REACTIONS, contact Intercept Pharmaceuticals, Inc. at 1-844-782-ICPT or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Intercept

305 Madison Avenue | Morristown, NJ 07960 | T: 1-844-782-4278 | info@interceptpharma.com

OCALIVA®
obeticholic acid