OCALIVA®
obeticholic acid

I am currently taking OCALIVA® (obeticholic acid)

MY DISCUSSION GUIDE

Get the most out of your OCALIVA treatment.

This guide is not intended to replace the advice of your healthcare team. All decisions regarding dosing and drug administration should be made by the prescriber using his/her clinical judgment. **Highlight the questions you want to address with your healthcare team and get the support you need to stay on track with your primary biliary cholangitis (PBC) treatment plan.**

PBC

What is alkaline phosphatase (ALP) and what does it tell us about my PBC?

Why is it important to keep my ALP low?

How often should I get liver function tests (LFTs), including ALP?

What does lower ALP mean for my liver health?

IMPORTANT SAFETY INFORMATION

What is OCALIVA?

OCALIVA (obeticholic acid) is a prescription medicine used for the treatment of primary biliary cholangitis (PBC) in adult patients. OCALIVA is taken in combination with another medicine called ursodeoxycholic acid (UDCA), or, for people who cannot tolerate UDCA, OCALIVA can be taken by itself.

The effectiveness of OCALIVA in these patients is based on a study that showed a reduction in the liver enzyme alkaline phosphatase (ALP). There is no clinical information currently available to show if patients treated with OCALIVA live longer or if their symptoms improve. 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 been told by a healthcare provider that you have complete biliary obstruction. Report to your healthcare provider immediately if you develop symptoms of complete biliary obstruction.

Please see additional Important Safety Information on pages 4 and 5.
Please visit ocaliva.com for the full Prescribing Information for OCALIVA 5mg and 10mg tablets.

OCALIVA® (obeticholic acid)

How can I tell if OCALIVA is working for me?

How does OCALIVA help me lower my ALP?

What dose of OCALIVA is right for me? Will it ever need to be adjusted?

How is OCALIVA administered?

What should I do if I experience a side effect or symptom? Who should I contact at your office?

Your treatment plan

What are the treatment goals associated with taking OCALIVA?

How important is it that I take OCALIVA exactly as prescribed? What if something changes in the way I'm feeling?

How long will I have to take OCALIVA?

IMPORTANT SAFETY INFORMATION

What are the possible side effects of OCALIVA?

OCALIVA may cause serious side effects, including:

- **Liver-Related Adverse Reactions.** Liver-related adverse reactions including jaundice (yellow pigmentation of skin and whites of the eyes), worsening ascites (accumulation of fluid in the stomach) and primary biliary cholangitis flare (sudden worsening of PBC symptoms) have been observed in clinical trials, as early as one month after starting treatment with OCALIVA 10 mg once-daily up to 50 mg once-daily (up to 5-times the highest recommended dosage). Your healthcare provider may do blood tests periodically during your treatment with OCALIVA to check how well your liver is working. Report to your healthcare provider immediately if you develop any symptoms of worsening liver disease.

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Your treatment plan (cont'd)

How can I tell if a symptom is from my PBC or from OCALIVA® (obeticholic acid)? If I experience a side effect, should I stop taking OCALIVA?

If I continue to experience symptoms, how do I know OCALIVA is working for me?

Are there support services available to help me stay on my OCALIVA treatment plan? What if I need help working with my insurance company?

Is there financial assistance available to help me start and stay on OCALIVA?

If my insurance coverage has changed, who should I contact about continuing my treatment?

When should I call my specialty pharmacy regarding an OCALIVA refill?

IMPORTANT SAFETY INFORMATION

What are the possible side effects of OCALIVA?

The most common side effects of OCALIVA include: pruritus (severe itching of the skin), fatigue (feeling tired all over), stomach pain and discomfort, rash, arthralgia (joint pain), oropharyngeal pain (pain in the middle part of the throat), dizziness, constipation, abnormal thyroid function and eczema (inflammation of the skin).

These are not all the possible side effects associated with OCALIVA. Tell your healthcare provider if you have any side effect that bothers you or does not go away.

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- **Severe Pruritus.** Cases of severe pruritus have occurred in patients being treated with OCALIVA. Severe pruritus consists of intense or widespread itching, interfering with activities of daily living, or causing severe difficulty in staying asleep, or intolerable discomfort, and typically requiring medical interventions. Your healthcare provider may recommend taking bile acid resins or antihistamines, OCALIVA dosage reduction, and/or temporary interruption of OCALIVA dosing to help manage the symptoms of severe pruritus. Be sure to tell your healthcare provider if pruritus develops or worsens during treatment with OCALIVA.
- **Decreases in HDL-C Cholesterol.** Decreases in HDL-C (good cholesterol) have been observed in patients taking OCALIVA. Your healthcare provider may check your lipid levels periodically during your treatment with OCALIVA.

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What should I tell my healthcare provider before taking OCALIVA® (obeticholic acid)?

Before taking OCALIVA, tell your healthcare provider about:

- **all of your medical conditions**
- **all of the medicines you take**, including prescription and over-the-counter (OTC) medicines, vitamins and herbal supplements. OCALIVA and other medicines may affect each other, so be sure to tell your healthcare provider if you start a new medicine.

OCALIVA may affect the way other medicines work, and other medicines may affect how OCALIVA works.

Especially tell your healthcare provider if you take:

- Bile Acid Resins, such as cholestyramine, colestipol or colesevelam. Some medicines used to lower blood cholesterol levels, so-called bile acid resins may reduce the effectiveness of OCALIVA. If you take any of these medicines, take OCALIVA at least 4 hours before or 4 hours after taking the bile acid resin, or at as great an interval as possible.
- Warfarin. Your International Normalized Ratio (INR) (which measures how your blood clots) is decreased when warfarin is taken along with OCALIVA. Your physician may need to monitor your INR and/or adjust your dosage of warfarin to keep your INR in a target range while you are taking both warfarin and OCALIVA. Your healthcare provider may need to monitor the co-administration of OCALIVA and warfarin.
- CYP1A2 Substrates with Narrow Therapeutic Index. Obeticholic acid, the active ingredient in OCALIVA, may increase the exposure to certain drugs that are CYP1A2 substrates, such as theophylline and tizanidine. Your healthcare provider may, as needed, monitor CYP1A2 Substrates with Narrow Therapeutic Index when they are taken along with OCALIVA.

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

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