

IMPORTANT SAFETY INFORMATION (Cont'd)

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 (pruritus).** Itching is a common side effect and can sometimes become severe (intense itching or itching over much of 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.
- **Lower HDL-C** ("good" cholesterol). OCALIVA can lower high levels of HDL-C. Your healthcare provider will check your cholesterol levels during treatment with OCALIVA.

The most common side effects of OCALIVA include: 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; dryness, irritation, redness, crusting or drainage of the skin (eczema).

These are not all the possible side effects of OCALIVA. Call your doctor 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.

The risk information provided here is not complete. To learn more, please talk to your healthcare provider.

Please see accompanying [Full Prescribing Information](#) and [Medication Guide](#) for OCALIVA.

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.

Currently on OCALIVA[®] (obeticholic acid)
MY HEALTHCARE TEAM DISCUSSION GUIDE
Get the most out of your treatment with OCALIVA

Highlight the questions that apply to you and bring them to your next appointment.

This guide is not intended to replace the advice of your healthcare team. All decisions regarding primary biliary cholangitis (PBC) treatment should be made by the prescriber using his/her clinical judgment.

ABOUT OCALIVA?

How do I know that OCALIVA is working, and how soon will I know?

Can OCALIVA help people who have already lowered their alkaline phosphatase (ALP) levels with another medicine?

Could OCALIVA work for me if I cannot tolerate ursodeoxycholic acid (UDCA)? How does OCALIVA work differently from UDCA?

Can I take OCALIVA if I am taking other medicines for my PBC? What about taking it with medicines for other health conditions?

WHAT TO EXPECT

Will the effectiveness of OCALIVA change over time?

What should I do if I miss a dose of OCALIVA?

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

Can my dose be changed to help manage side effects?

What are we trying to achieve by adding OCALIVA to my treatment plan? Can you help me set short- and long-term goals?

NOTES

INDICATION

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. It is not known if OCALIVA is safe and effective in children.

IMPORTANT SAFETY INFORMATION

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

OCALIVA may cause serious side effects including:

Worsening of liver problems or liver failure, in some cases leading to liver transplant or death, has happened in people with primary biliary cholangitis (PBC) with liver cirrhosis when taking 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 if it is safe for you to start taking OCALIVA and safe for you to continue taking OCALIVA.

Please see additional Important Safety Information throughout and accompanying [Medication Guide](#) and Full [Prescribing Information](#), including Boxed Warning, for OCALIVA 5 mg and 10 mg tablets. Rx only.

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