

YOU AND OCALIVA® (OBETICHOLIC ACID)

The importance of staying on treatment

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.

Your liver health is important. Your doctor prescribed OCALIVA because it works in a unique way to lower your ALP.



Reducing ALP levels

OCALIVA lowers your alkaline phosphatase (ALP) level by reducing the damaging buildup of bile acids in your liver.

- ALP is a liver health marker that can show damage to the liver caused by primary biliary cholangitis (PBC).

If you tolerate OCALIVA and your doctor thinks you could further lower your ALP level, he or she may increase your dose from 5 mg to 10 mg after the first 3 months of treatment.

If you still experience symptoms of pruritus and fatigue during treatment, know that they are not necessarily related to how far the disease has progressed, and OCALIVA may still be working to lower your ALP.



Staying on track over time

It's important to stay in touch with your doctor to talk about your treatment and to keep track of your ALP level by getting it tested every 3 to 6 months.

If you experience any side effects, talk to your healthcare provider about managing them so you can stay on course with your treatment plan.

The **most common side effects** include pruritus (severe itching of the skin), fatigue (feeling tired all over), and stomach pain and discomfort. Other common side effects include 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).

Staying up-to-date with your liver health

My healthcare provider contact

Name: _____

Phone number: _____

Current liver marker test results

ALP: _____

Bilirubin: _____

Next appointment

Date: _____

Time: _____

Follow-up liver marker test results

ALP: _____

Bilirubin: _____

Support for you and your liver health



Talk to your healthcare provider

Your healthcare provider is here for you and can help you with any issues along the way.



Visit ocaliva.com

Learn more about your treatment and find additional resources.

Please see [Medication Guide](#) and full [Prescribing Information](#), including Boxed Warning, for OCALIVA 5 mg and 10 mg tablets. Rx only.

**OCALIVA**
obeticholic acid

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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.

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”; 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 and chills; light-headedness; less frequent urination

Who should not take OCALIVA?

Do not take OCALIVA if you:

- have PBC with liver cirrhosis with symptoms such as fluid in the stomach-area or confusion (decompensated liver cirrhosis) or with abnormalities in certain tests that check your liver.
- have a complete blockage of 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 (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 click here for [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.

