

MEDICATION GUIDE
OCALIVA® (o-CAL-eh-vah)
(obeticholic acid) tablets

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

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.

OCALIVA can 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.

- **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

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 in 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.

Do not take OCALIVA if you:

- have a complete blockage of the bile ducts in your liver or gall bladder.

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 breast milk. 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.

How should I take OCALIVA?

- Take OCALIVA exactly as your healthcare provider tells you to.
- Do not take more OCALIVA than your healthcare provider tells you to.
- Take OCALIVA with or without food.
- If you take a bile acid binding resin, take OCALIVA at least 4 hours before **or** 4 hours after you take your bile acid binding resin. If this is not possible, space the time between taking OCALIVA and your bile acid binding resin as far apart as possible.
- If you take too much OCALIVA, call your healthcare provider or get emergency medical help right away.

What are the possible side effects of OCALIVA?

OCALIVA can 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 of OCALIVA 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 your treatment with OCALIVA.

The most common side effects of OCALIVA include:

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| • tiredness | • dizziness | • fever |
| • stomach pain and discomfort | • constipation | • changes in how your thyroid gland works |
| • rash | • swelling in your hands, ankles, or feet | • dryness, irritation, redness, crusting or drainage of the skin (eczema) |
| • joint pain | • fast or irregular heartbeat | |
| • mouth and throat pain | | |

These are not all the possible side effects of OCALIVA. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store OCALIVA?

- Store OCALIVA at room temperature between 68°F to 77°F (20°C to 25°C).

Keep OCALIVA and all medicines out of the reach of children.

General information about the safe and effective use of OCALIVA.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use OCALIVA for a condition for which it was not prescribed. Do not give OCALIVA to other people, even if they have the same symptoms that you have. It may harm them. You can ask your pharmacist or healthcare provider for information about OCALIVA that is written for health professionals.

What are the ingredients in OCALIVA?

Active ingredient: obeticholic acid

Inactive ingredients: microcrystalline cellulose, sodium starch glycolate, magnesium stearate

Film coating: Opadry II (Yellow) containing polyvinyl alcohol-part hydrolyzed, titanium dioxide, macrogol (polyethylene glycol 3350), talc, iron oxide yellow

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For more information, go to www.OCALIVA.com or call 1-844-782-4278.