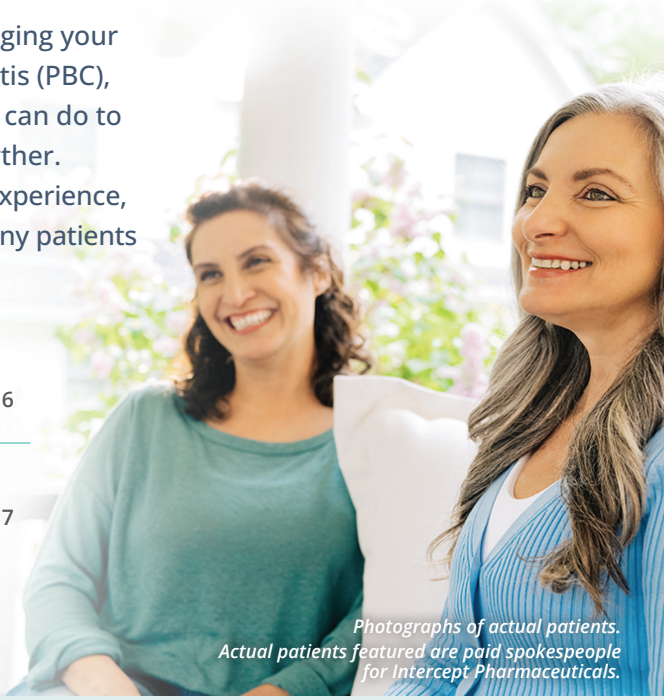
OCALIVA®
obeticholic acid

Find your way forward with OCALIVA

When it comes to managing your primary biliary cholangitis (PBC), there may be more you can do to take your treatment further. With 9 years of clinical experience, OCALIVA has helped many patients lower their ALP further.



Photographs of actual patients. Actual patients featured are paid spokespeople for Intercept Pharmaceuticals.

Rosalía, 56
Joined #TeamOCALIVA in 2016

Leslie, 61
Joined #TeamOCALIVA in 2017

ALP, alkaline phosphatase.

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.

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What is PBC?

PBC is a chronic, progressive autoimmune liver disease.
If you have PBC:

- your body may attack tubes in your liver (bile ducts), causing a buildup of toxic bile acid (cholestasis)
- that bile buildup can lead to further inflammation and liver cell damage
- ongoing liver cell damage can lead to liver scarring (fibrosis) and permanent liver damage (cirrhosis)

It is important to start treatment early because medicine may work best in people whose PBC is still in the early stages.

Spotting the signs

PBC can be difficult to detect because sometimes there may be no symptoms at all. Symptoms can also come and go. Some of the most common symptoms of PBC are:

Pruritus
(Itchiness)

Fatigue

Other symptoms include, but are not limited to, dry eyes and mouth, and trouble remembering or concentrating.

70% Up to **70% of people with PBC** experience pruritus.

What are the goals for PBC?

Monitoring your PBC progression means focusing on overall liver health, which includes (but is not limited to) disease progression, liver biochemical markers (biomarkers), liver stiffness, and treatment response.

To avoid negative outcomes, such as needing a liver transplant or death, it's important to:

- bring levels of key biochemical markers (biomarkers) of liver health down to normal (or near normal) levels and keep them there
- prevent the progression of "liver stiffness" (fibrosis)

Talk to your healthcare team about your personal short- and long-term PBC treatment goals.

Monitoring liver health

Historically, some doctors would only track ALP and bilirubin levels to see how your PBC was progressing. However, to properly assess PBC and its progression, it's important to track a range of biomarkers and monitor your fibrosis.

Key biomarkers of PBC progression are:

- ALP (alkaline phosphatase)
- GGT (gamma-glutamyl transferase)
- ALT (alanine aminotransferase)
- AST (aspartate aminotransferase)
- Total bilirubin
- Albumin
- Platelets

One treatment goal of PBC is to normalize or near normalize biomarker levels and keep them there. Even with stable levels, if they remain high, you could be at risk for further disease progression.

OCALIVA® (obeticholic acid) may help you reach your treatment goals

OCALIVA is a **once-daily pill** shown to help lower ALP even further than when taking ursodeoxycholic acid (UDCA) alone.*

*OCALIVA is a prescription medicine used to treat PBC in combination with UDCA in adults who have not responded well enough to UDCA, or alone for adults who cannot tolerate UDCA.

OCALIVA works differently to address PBC

OCALIVA

OCALIVA activates a particular receptor called farnesoid X receptor (FXR)

OCALIVA + UDCA
work better together

Up to 1 in 2 people may not respond to UDCA alone, with their ALP levels remaining too high even if they are lower than they were before. OCALIVA can help lower ALP even further

UDCA

UDCA works by diluting the bile acid pool by replacing/displacing toxic bile buildup

OCALIVA works alone, too

OCALIVA can also be taken without UDCA (known as monotherapy) if UDCA is not tolerated.

IMPORTANT SAFETY INFORMATION (cont'd)

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.

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~5x more patients who took OCALIVA showed a response to treatment in a 12-month clinical study*

OCALIVA® obeticholic acid

UDCA alone	OCALIVA 5 mg → 10 mg†	OCALIVA 10 mg
(73 out of 216 patients)	(70 out of 216 patients)	(73 out of 216 patients)
10%	46%	48%
of patients responded to treatment	of patients responded to treatment	of patients responded to treatment

Treatment response was defined by:

- ALP was less than 1.67 times the upper limit of normal‡
- ALP decreased by at least 15%
- Bilirubin levels were within the normal range§

- Average ALP levels in both OCALIVA treatment groups were reduced by more than 30% in 1 year vs ~5% with UDCA alone*
- Some people taking OCALIVA saw a reduction in ALP levels as early as 2 weeks after starting treatment

*In the study, patients taking OCALIVA were also taking UDCA, except for 16 patients (7%) who were intolerant and did not receive concomitant UDCA: 6 patients (8%) in the OCALIVA 10 mg arm, 5 patients (7%) in the OCALIVA titration arm, and 5 patients (7%) in the placebo arm.

†In the 5 mg→10 mg titration group, 36 patients stayed at 5 mg and 33 were titrated to 10 mg after 6 months.

‡Many liver health markers such as ALP have a range of values that are considered normal. The top of that range is called the upper limit of normal.

§Bilirubin is a separate marker of overall liver health. It is measured with a blood test. Bilirubin levels are more likely to be increased in people with PBC with advanced disease and liver damage.

For over 6 years, the impact of OCALIVA on markers of cholestasis and inflammation, and fibrosis, has been studied

Visit OCALIVA.com to learn more about this study. It is not known if taking OCALIVA will improve your chance of survival or improve your symptoms of PBC. **There are ongoing studies to assess outcomes with OCALIVA over the long term.**

What should I know about potential side effects?

Pruritus is a common symptom of PBC and can also be a side effect of taking OCALIVA® (obeticholic acid)—**generally appearing within the first month of treatment.**

When discussing a pruritus management plan with your doctor, remember to **keep your PBC treatment goals top of mind.**

In a clinical study of OCALIVA, **only 1% of people who started on 5 mg discontinued treatment due to pruritus*** vs 10% of people who started on 10 mg; no patients in the placebo group discontinued.

*1 patient out of 70 (1%) discontinued in the 5–>10-mg group, 7 out of 73 (10%) discontinued in the 10 mg group and no patients in the placebo group (n=73) discontinued.

97%
of patients

The majority of people (193 out of 198) **who completed the study at 12 months chose to continue taking OCALIVA** in a long-term follow-up study.†

†Of 198 patients who completed the double-blind phase, 193 (97%) elected to enter the open-label extension.

Connect with a real patient and get your questions answered

The **OCALIVA Connect Mentor Program** helps you get the answers you need about treatment with OCALIVA, as well as tips for managing and living with PBC. **Call 1-833-508-9362 to schedule your session with an OCALIVA Connect Mentor today!**

IMPORTANT SAFETY INFORMATION (cont'd)

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

Starting and staying on OCALIVA

OCALIVA® obeticholic acid

How to take OCALIVA

OCALIVA is a once-daily pill available in 2 dosage strengths: 5 mg and 10 mg. Your doctor will work with you to determine the best dose for you.

Your doctor will start you on a dose of OCALIVA 5 mg. After 3 months, your doctor may **increase your dose to 10 mg,** based on your lab results.

Here are some important things to know about OCALIVA:

Tell your healthcare provider about any other prescription or over-the-counter medicines, herbal remedies, vitamins, or other supplements you are taking or plan to take.

4
hours

If you are taking a bile acid resin, take OCALIVA at least 4 hours before or 4 hours after.

OCALIVA can be taken with or without food.

You'll get your OCALIVA prescription shipped directly to you from a specialty pharmacy.

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Proactive lifestyle tips to help manage pruritus

Even if you're not currently experiencing itching, there are certain things you can do to try to prevent it. If you experience pruritus while taking OCALIVA® (obeticholic acid), talk to your healthcare provider.

Adopt good sleep habits

Pruritus can cause sleep deprivation. Patients also report that itching can become worse at night. Practicing good sleep habits and strategies can help improve sleep duration and quality.

- **Play "white noise"** in the bedroom
- **Use aromatherapy and massage**

Practice good hygiene

- **Take cool showers**
- **Apply a daily moisturizer**, such as Eucerin®

Use topical treatments & medications

- **Apply topical corticosteroids,** such as hydrocortisone
- **Add an antihistamine**

Looking for more proactive lifestyle tips?

Scan the QR code or **visit OCALIVA.com** for the Managing Pruritus Brochure to get more tips to help manage symptoms of PBC.

Ask your doctor for a code to get your Pruritus Management Kit today

OCALIVA offers a **Pruritus Management Kit** to help you take proactive steps to managing pruritus (itching) with nonprescription remedies. Be sure to follow your doctor's instructions and always use the kit under their care.

Interconnect® offers patient support to help you start and stay on OCALIVA

OCALIVA® obeticholic acid

With Interconnect, you'll be assigned a dedicated care coordinator that will be with you every step of the way, even after you get your first OCALIVA shipment.

99% of commercially insured patients are eligible to pay $0 when a copay card is applied*

Interconnect is dedicated to helping you get access to OCALIVA. You may be able to **pay as little as $0 for your OCALIVA prescription**.*

Interconnect® SUPPORT SERVICES
Integrated access and support by Intercept

Whether you have **commercial insurance, Medicare/Medicaid, or are uninsured, a Care Coordinator at Interconnect** can help you find the most affordable way to get OCALIVA.

Scan the QR code, call 1-844-622-4278 or **visit Interconnectsupport.com** to learn more

*Offer not valid for patients enrolled in Medicare, Medicaid, or other federal or state healthcare programs. See program terms, conditions, and eligibility at www.OCALIVA.com/copay-terms.

IMPORTANT SAFETY INFORMATION (cont'd)
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.

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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 or visit OCALIVA.com.

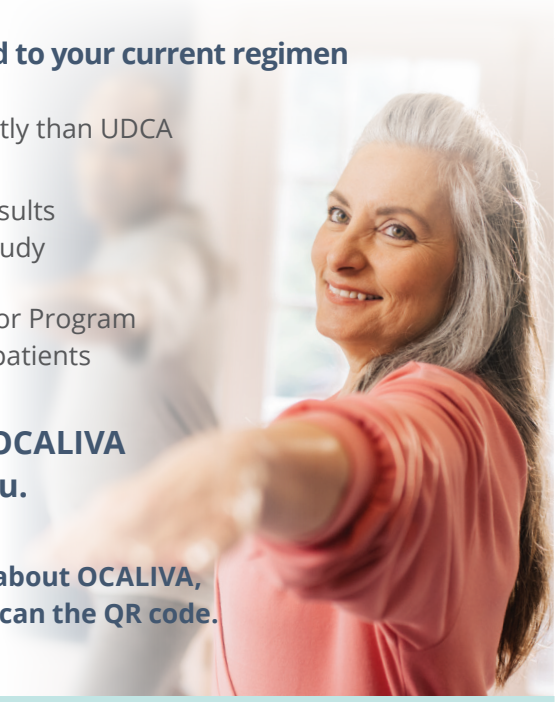
Available by prescription only.

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.

OCALIVA®
obeticholic acid

OCALIVA can help take your treatment further

A once-daily treatment added to your current regimen



- OCALIVA works differently than UDCA
- OCALIVA offers rapid results based on a 12-month study
- OCALIVA Connect Mentor Program connects you with real patients

Ask your doctor if OCALIVA may be right for you.

For more information about OCALIVA, visit OCALIVA.com or scan the QR code.

$0

99% of commercially insured patients are eligible to pay $0 when a copay card is applied*

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Intercept
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