



**ROSALÍA, 53**  
Joined Team OCALIVA in 2016



**LESLIE, 58**  
Joined Team OCALIVA in 2017

Photographs of actual patients.

## Join a team of people who've found a way forward with OCALIVA

Even if you're already on treatment, there may be more you can do to manage your primary biliary cholangitis (PBC).

**#TeamOCALIVA**



### 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 on pages 16 and 17 and [Medication Guide](#) and [Full Prescribing Information](#), including Boxed Warning, for OCALIVA 5 mg and 10 mg tablets.



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Photograph of actual patients.

### 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.

**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

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# PBC is a progressive condition that gets worse over time without proper treatment.

Primary biliary cholangitis (PBC) is an autoimmune disease, which means the body attacks itself. **With PBC, the body attacks your liver**—it causes the bile ducts to become damaged and filled with toxic bile acid buildup.

**This bile acid buildup caused by PBC can lead to harmful scarring in the liver.** As scar tissue replaces healthy liver tissue, liver function gets worse and worse. If not treated properly, PBC may lead to liver damage and, in some cases, even the need for a liver transplant.

**The most common symptoms are pruritus (severe itching of the skin) and fatigue (feeling tired all over).**

And it's normal for these symptoms to appear, disappear, or continue at any stage. The presence of symptoms or how severe they feel is **not** related to how far the disease has progressed, or how well your treatment is working.

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**If you experience pruritus or fatigue, talk to your healthcare team and ask:**

- ✓ Are there any prescription or over-the-counter medications or products that may help with pruritus?
- ✓ Are there any prescription medications to help with fatigue? (Especially if you feel very sleepy during the day)
- ✓ Are there any foods, types of exercise, or other lifestyle changes that may help?

## 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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## You can track the effectiveness of your PBC treatment with a simple blood test.

ALP (alkaline phosphatase) and bilirubin levels are 2 key markers of liver health. Monitoring your ALP and bilirubin over time, with simple blood tests (managed by your healthcare provider), can help slow your liver disease progression.



**ALP and bilirubin levels can be measured using a simple blood test.**



**When ALP or bilirubin levels are higher than normal, it can be a sign of liver damage.**



**Getting ALP and bilirubin levels closer to normal can reduce your risk of needing a liver transplant.**

It is not known if taking OCALIVA will improve your chance of survival or improve your symptoms of PBC.



Photograph of an actual patient.

**Tracking your levels with liver function tests every 3 to 6 months can tell your doctor how your PBC is progressing.**

Record and track all test results. Keep all results together and share them with your healthcare team at each visit.

  
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®

# Work with your healthcare team to set your PBC treatment goals.

General PBC treatment goals can include:

- ✓ Lowering ALP levels (as close as possible to the normal range)
- ✓ Keeping bilirubin levels within normal range
- ✓ Slowing the progression of liver disease

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

## Did you know? PBC treatment is a lifelong commitment.

- Ongoing treatment is needed for PBC. **Ursodiol (also called ursodeoxycholic acid or UDCA)** is the **most common treatment** for people with any stage of PBC.
- Some people with PBC are unable to tolerate ursodiol and require a different treatment option.
- **Even if you're already on treatment, there may be more you can do to manage PBC.**

The effectiveness of OCALIVA is based on a study that showed a reduction in the liver enzyme 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.

### 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?"** on page 16.

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Photograph of an actual patient.

By working with your healthcare team to add OCALIVA to your treatment plan, you can take the next step in your PBC care.

### OCALIVA works with ursodiol

If you're not responding well enough to ursodiol (ursodeoxycholic acid or UDCA), OCALIVA may be beneficial to you. OCALIVA is an add-on treatment—so it can reduce ALP more than ursodeoxycholic acid could alone, but you also don't have to give up your ursodiol.

### And OCALIVA works alone, too

For those who can't tolerate ursodiol, OCALIVA can also be taken alone and can still be effective in treating PBC by lowering ALP.



The **first and only FDA-approved** add-on\* treatment for PBC supported by **6 years** of clinical trial data

\*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.

  
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# OCALIVA is proven to deliver significant, sustained ALP reductions.

OCALIVA has been studied in a clinical trial where people either took OCALIVA and ursodiol (ursodeoxycholic acid or UDCA) together—or OCALIVA by itself (if they couldn't tolerate ursodiol). Almost half of the people who took OCALIVA were considered "responders" to treatment.

**Most people in this study took OCALIVA in combination with ursodiol. People were considered "responders" if:**

- ✓ 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†



## Some people taking OCALIVA saw a reduction in ALP levels as early as 2 weeks after starting treatment.

The effectiveness of OCALIVA in these patients is based on a study that showed a reduction in the liver enzyme 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.

\*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.

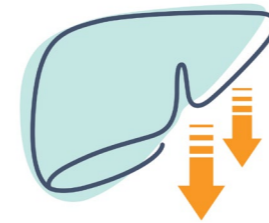
†Bilirubin is a separate marker of overall liver health. It is measured with a blood test. Bilirubin levels are more likely to be increased in people with PBC with advanced disease and liver damage.

### IMPORTANT SAFETY INFORMATION (Cont'd)

- **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.

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# OCALIVA works in a unique way to reduce toxic bile acid buildup caused by PBC.



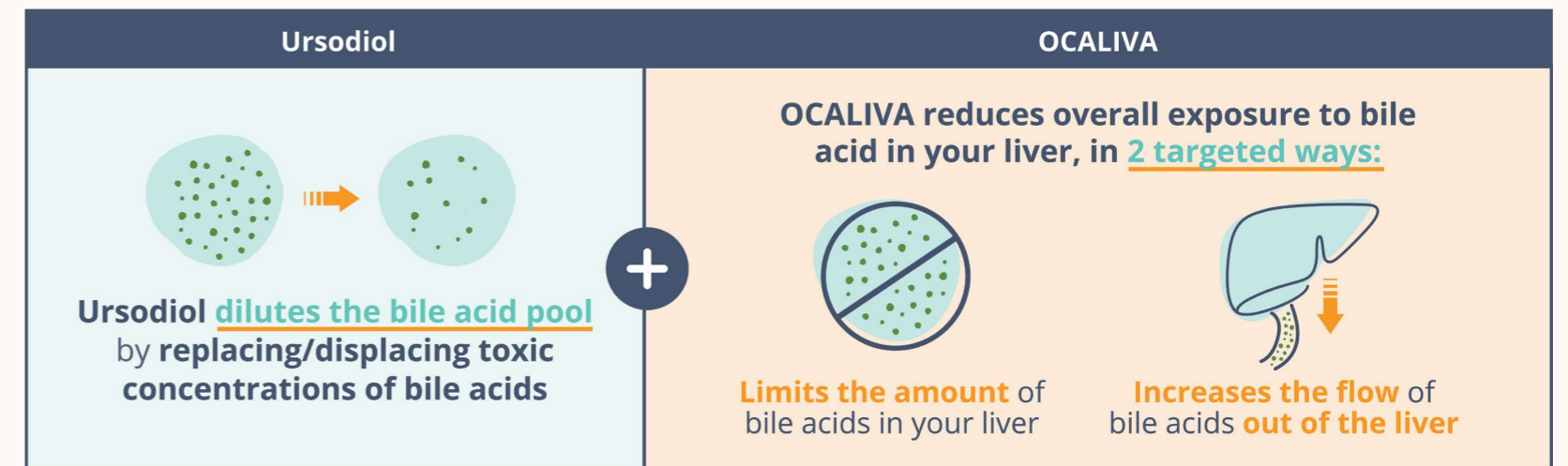
OCALIVA can help you lower your ALP level by **reducing bile acid buildup in the liver.**



OCALIVA works by **activating a receptor inside your body** (called farnesoid X or FXR).‡

This helps increase the flow of bile acids out of the liver and reduces exposure to toxic bile acids.

OCALIVA treats PBC differently than ursodiol (ursodeoxycholic acid or UDCA), **working alongside it.**



OCALIVA, **when added to ursodiol**, may help lower your ALP more than ursodiol alone.



Ask your healthcare team if adding OCALIVA could help you.

‡Farnesoid X (FXR) is a receptor that's located in your liver. It is also known as the "bile acid receptor."



# Side effects are possible with any prescription medication, including OCALIVA.

The most common side effects include:



**Pruritus**  
(severe itching of the skin)



**Fatigue**  
(feeling tired all over)



**Stomach pain and discomfort**

Other common side effects include 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, and eczema (skin dryness, irritation, redness, crusting, or drainage).

These are not all the possible side effects associated with OCALIVA. Call your healthcare provider for medical advice about side effects.

**PBC-related pruritus and fatigue can be the result of the treatment (a side effect), the condition (a symptom), or both.**

Tell your healthcare team if you notice any changes after starting treatment with OCALIVA.

If you experience pruritus while taking OCALIVA, ask your healthcare provider about options. They'll be able to recommend possible treatments or lifestyle changes to help soothe your symptoms.

## IMPORTANT SAFETY INFORMATION (Cont'd)

- **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.

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Photograph of an actual patient.

OCALIVA is working to manage your PBC and lower your ALP levels, even if you don't notice a difference in how you feel.

**It's important to take OCALIVA exactly as prescribed. If you are experiencing any side effects or symptoms, it's important to talk to your healthcare team. Ask them:**

**1. Are there any medications that may help manage symptoms or side effects?**

Ask if there are any prescription medications (eg, bile acid-binding resins), over-the-counter medications (eg, antihistamines), or products that may help with itching. There may also be medications to help with fatigue, especially if you feel very sleepy during the day.

**2. Are there any lifestyle changes that can help manage the symptoms or side effects?**

Ask your healthcare team if there are any foods, types of exercise, or other lifestyle changes that may help manage your symptoms or side effects.

**3. Can my dose be changed to help manage side effects?**

If your healthcare provider determines that your itching or fatigue may be a side effect of treatment, he or she may be able to lower your dose or make changes to how often you take OCALIVA and still effectively treat your PBC. Ask your healthcare provider if either of these options is right for you. In some cases he or she may ask you to stop taking OCALIVA.



**Always talk to your healthcare team before making any changes to your PBC treatment plan.**



# It's important to take OCALIVA exactly as prescribed by your healthcare provider.



## Follow these basic instructions for taking OCALIVA:

- Take the exact dose prescribed by your healthcare provider (5 mg or 10 mg)
- 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
- If you are taking a bile acid resin, take OCALIVA at least 4 hours before or 4 hours after taking the bile acid resin, or at as great an interval as possible
- OCALIVA may be taken with or without food

It's possible that after 3+ months on OCALIVA and carefully monitoring your lab tests, your doctor may change your dose from 5 mg to 10 mg to help manage your PBC even better.



Photograph of an actual patient.

OCALIVA is still working to fight PBC inside your body—even when you don't feel a difference in your daily life. That's why it's extremely important to keep taking it as prescribed, even if:

- ✓ You feel well
- ✓ Your ALP levels are lower (closer to the normal range)
- ✓ Your symptoms improve

Taking OCALIVA as prescribed by your doctor will give you the best chance at success in treating PBC—which is why you should never stop taking it unless your doctor has told you to do so.

## IMPORTANT SAFETY INFORMATION (Cont'd)

**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.

## IMPORTANT SAFETY INFORMATION (Cont'd)

- 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.

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# Personalized support and resources

We're proud to offer a wide range of resources and educational content for people living with PBC and taking OCALIVA.

## Educational videos

Browse video gallery and learn from interviews with PBC specialists (doctors, nurses, people living with PBC).

## Ongoing PBC events

See upcoming educational PBC events.

## Downloadable resources

Download questions to ask your doctor, resources for friends and family, as well as specialty pharmacy information.

Visit [OCALIVA.com](https://ocaliva.com) to learn more

## Free mentor phone calls

Talk to another person taking OCALIVA candidly and ask any questions you may have.

1-833-508-9362

Photograph of an actual patient.

## IMPORTANT SAFETY INFORMATION (Cont'd)

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.

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# Interconnect<sup>®</sup> is here to help you start and stay on OCALIVA

**Interconnect<sup>®</sup>**  
SUPPORT SERVICES



Your dedicated Care Coordinator will help you with:



## Financial assistance

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.



## Personalized support

We'll be in touch along the way to help you stay on track, answer questions, and address any concerns you may have.



## Education

We'll share tools and resources to help you better understand your treatment with OCALIVA.

\$0

You may be able to pay as little as \$0 for your OCALIVA prescription\*



Scan the QR code, call 1-844-622-4278 or visit [interconnect.com](https://interconnect.com) to learn more.

\*Except where prohibited by state law. Some people will not qualify for certain service offerings. Intercept reserves the right to rescind, revoke, or amend this offer without notice. For full terms and conditions of the co-pay program, visit [ocaliva.com/copay-terms](https://ocaliva.com/copay-terms)

  
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## INDICATION

### What is OCALIVA?

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**OCALIVA may cause serious side effects including:**

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**Tell your healthcare provider right away if you have any of the following symptoms of worsening liver problems** during treatment with OCALIVA:

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### 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.

**Please see additional Important Safety Information on reverse.**



## 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).

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**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 [Full Prescribing Information](#) and [Medication Guide](#) for OCALIVA or visit [ocaliva.com](http://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](http://www.fda.gov/medwatch).**



Photograph of actual patients.



See the latest  
**#TeamOCALIVA** events  
for people living with PBC

# The first and only FDA-approved add-on\* treatment for PBC

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