



Caring for someone with PBC

#TeamOCALIVA is here to help you learn about primary biliary cholangitis (PBC), treatment, and ways you can help support someone with PBC.

Photographs of actual patients.

ROSALÍA, 53

Joined Team OCALIVA in 2016

LESLIE, 58

Joined Team OCALIVA in 2017



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?

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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.

Please see additional Important Safety Information on pages 12 and 13 and [Medication Guide](#) and Full [Prescribing Information](#), including Boxed Warning, for OCALIVA 5 mg and 10 mg tablets. Rx only.



How to support someone with PBC

You care about someone who has primary biliary cholangitis (PBC). You want to help in any way that you can, but it can be hard to know what to say or do.

For people with PBC, having the support of friends and family can make a big difference. It helps to know that you have a team to be there for you along the way.

That's why it can be helpful for you to take the time to learn more on your own.

This brochure offers a great start to understanding more about PBC and treatment with OCALIVA® (obeticholic acid), the medicine that has been prescribed to your loved one.

Together, you and your loved one's healthcare providers can create a team of support your loved one can lean on when they need it most.



Photograph of actual patients.

“ One of the most supportive things is when a family member or friend says, ‘I’m going to educate myself so I can better understand what you’re going through.’ ”

— A person living with PBC

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

What is PBC?

PBC is a chronic, progressive liver disease.

PBC causes a person's immune system to attack the bile ducts in the liver, creating damage and inflammation. Over time, this can cause the liver to stop working as well as it used to.

Things to know about PBC:

- ✓ May involve the immune system
- ✓ Affects women up to 10 times more than men
- ✓ Seems to run in certain families
- ✓ Usually impacts people 20 to 70 years old

PBC is NOT related to alcohol or drugs—and it's NOT contagious. The cause of PBC is unknown. **It's no one's fault. PBC can just happen.**

People with PBC will need to have tests to see how their livers are doing.



Blood tests are done on a regular basis to check alkaline phosphatase (ALP) levels. **ALP and bilirubin** levels are 2 **key markers of liver health**. ALP is an enzyme related to the liver.



Tracking ALP can tell the **liver specialist** how well the person's current PBC treatment is working—and whether anything needs to be adjusted. These tests may be done often—every 3 to 6 months.

“ It's important for people to know that my body is attacking itself. I didn't do this to myself. Some days my body is in full attack mode. ”

— A person living with PBC

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

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Symptoms of PBC

The symptoms of PBC may vary for each person, but the most common are:



Fatigue

(Feeling tired all over)



Pruritus

(Itching of the skin)

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

That's why it is important for your loved one to work closely with their healthcare team on a treatment plan and keep up with regular ALP tests. Keep in mind, their side effects may continue even if the treatment is working, which is why regular tests are important!



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.

The symptoms you can't see

The most common symptoms of PBC (fatigue and pruritus) aren't visible to others. This disconnect between how a person looks on the outside and how he or she feels on the inside can be challenging for many reasons.

People without PBC may:

- ✓ Be tempted to think things are fine when they aren't
- ✓ Feel impatient when the person with PBC is unable to do the things he or she needs to do
- ✓ Find that the person with PBC is sometimes reluctant to admit how poorly he or she feels—because he or she doesn't want to be sick and disappoint others

Having PBC affects many parts of life, but there is more—much more—to life than PBC.

While it's a good idea to keep PBC in mind as you look for ways to help, it's also a good idea to focus on the person and the interests you share.



Photograph of actual patients.

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Fatigue: Not just any kind of tired

When a person feels fatigued, they may also feel drowsy and apathetic (a feeling of not caring about what happens). This type of fatigue impacts a person’s well-being and keeps them from doing the things they want and need to do.

Fatigue is common with PBC.

It can also be a side effect of treatment. You may think that because everyone feels tired sometimes that you know what the person with PBC is going through. But the fatigue that happens with PBC may not be just the normal kind of tired; it may be different and more severe than what you’d imagine.

There are things you can do to help.

Consider offering help in concrete and specific ways. For example:

Rather than saying	Say this instead
How can I help?	 <p>I’m stopping by to bring groceries. What do you need from the store?</p>
I wish I knew what to do.	 <p>Which night next week can I bring dinner—and what are you craving?</p>
I hate to see you this way.	 <p>I’ve got a free afternoon tomorrow. Can I do some laundry or run errands for you?</p>

You can also offer to simply be with the person who has PBC, doing whatever is enjoyable to him or her, even if it is a quiet activity. Sometimes the fatigue people feel can keep them from others, which can be lonely. **Knowing they have a team of support can be a big help.**

IMPORTANT SAFETY INFORMATION (Cont’d)

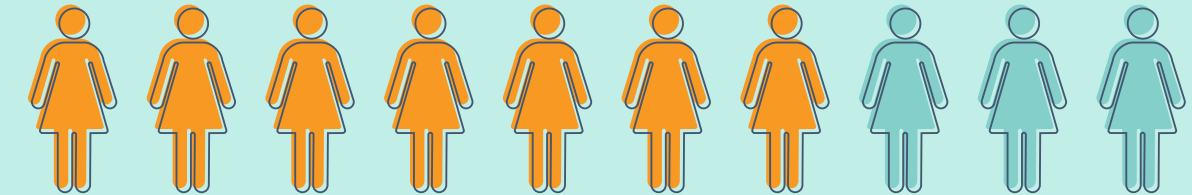
What are the possible side effects of OCALIVA?

OCALIVA may cause serious side effects, including:

- See “What is the most important information I should know about OCALIVA?” on page 12.
- **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.

Finding relief for pruritus

Up to **7 of every 10 people** with PBC may experience pruritus.



If your loved one is experiencing pruritus, be sure to encourage them to speak to their healthcare team.

Things your loved one can ask their healthcare team:

- ✓ Are there any prescription or over-the-counter medications or products that may help with pruritus?
- ✓ Are there any foods, types of exercise, or other lifestyle changes that may help?
- ✓ Can the dosage of my current medications be changed to help?



Photograph of an actual patient.

“ It feels like you’ve got something crawling on you. It’s hard to explain, because even when you scratch, it doesn’t really bring you relief. I do get a little itchy during the day, but it’s so bad at night. ”

— A person living with PBC

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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 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)

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).

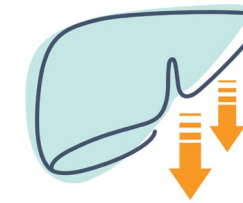
These are not all the possible side effects of OCALIVA. Call your doctor for medical advice about side effects.

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.

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



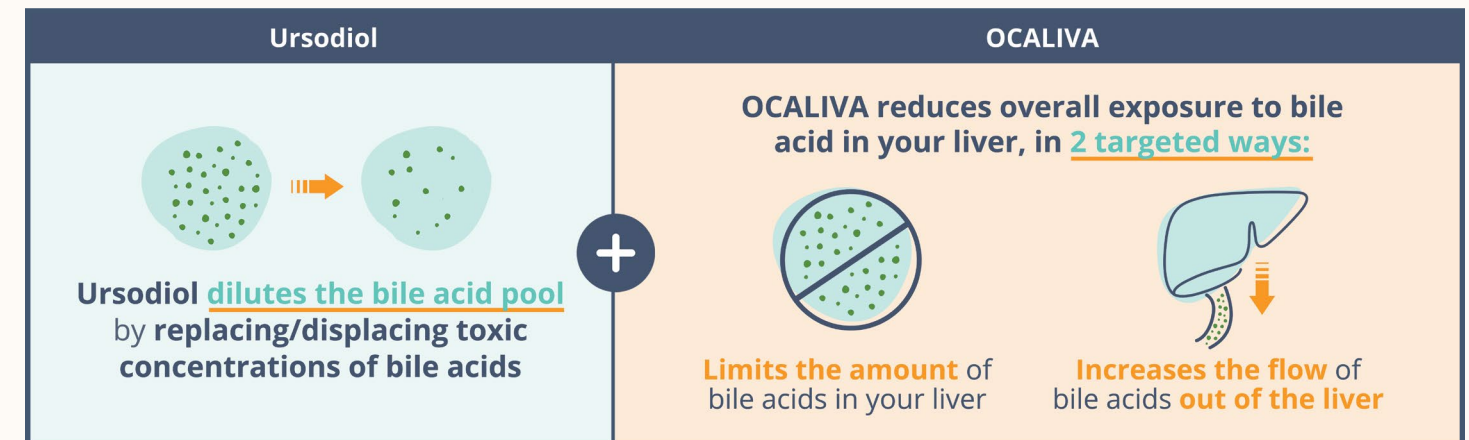
OCALIVA can help you lower your ALP level by **reducing bile acid buildup** in the liver.



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.

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

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Treatment can only help if it's taken properly



Photograph of an actual patient.

How can you help? Ensure treatment expectations are realistic.

To give the treatment a chance to help, the person with PBC needs to take it as prescribed. It's important to note that the treatment may be helping even if the person continues to experience pruritus and fatigue.

The person with PBC may at times wonder if treatment is helping or if it's worth continuing.

This is when their team of support comes in—to remind them how important it is to:



Continue with treatment for as long as the healthcare team recommends



Speak openly with all members of the healthcare team about how he or she is doing; there may be other ways to manage symptoms or side effects



Take it easy and give themselves permission to do less and focus on taking care of themselves



Photograph of an actual patient.

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 info.

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



Chat for free with an OCALIVA Connect Mentor

Your loved one can talk candidly with another person taking OCALIVA

1-833-508-9362

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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Please see 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.



Photograph of actual patients.

“ I don't let PBC rule my life or define who I am. I live with PBC. ”

— A person living with PBC



Learn more about PBC
with **#TeamOCALIVA**

Your support matters

Taking the time to learn more is a great way
to show the person in your life who has
PBC how much you care.



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obeticholic acid

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