



WELCOME TO YOUR WORLD OF PBC TREATMENT

Adding OCALIVA® (obeticholic acid) to your treatment plan starts here.

Photograph of an actual patient

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. There are ongoing studies to find out how OCALIVA works over a longer period of time.

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, 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.

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.

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 or visit ocaliva.com.
Rx only.



OCALIVA[®]
obeticholic acid



Contents:

Understanding PBC	4
PBC treatment goals	6
How adding OCALIVA may help	8
Side effects and symptoms	10
Taking OCALIVA	12
Personalized support	14



IMPORTANT SAFETY INFORMATION

What is the most important information I should know about 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”; or 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, or chills; light-headedness; less frequent urination

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 or visit ocaliva.com.

PBC is a progressive liver disease that gets worse over time without proper treatment.

Primary biliary cholangitis (PBC) is an autoimmune disease in which the body attacks the bile ducts and causes bile acids to build up in the liver.

This buildup can lead to harmful scarring in the liver. As scar tissue replaces healthy liver tissue, liver function becomes impaired. If not adequately treated, PBC may lead to liver damage and, in some cases, the need for a liver transplant.

It is normal for PBC symptoms to appear, disappear, or persist at any stage of the disease.

The presence or severity of symptoms is not related to how far the disease has progressed or how well your treatment is working.

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

If you experience pruritus or fatigue, talk to your healthcare team.



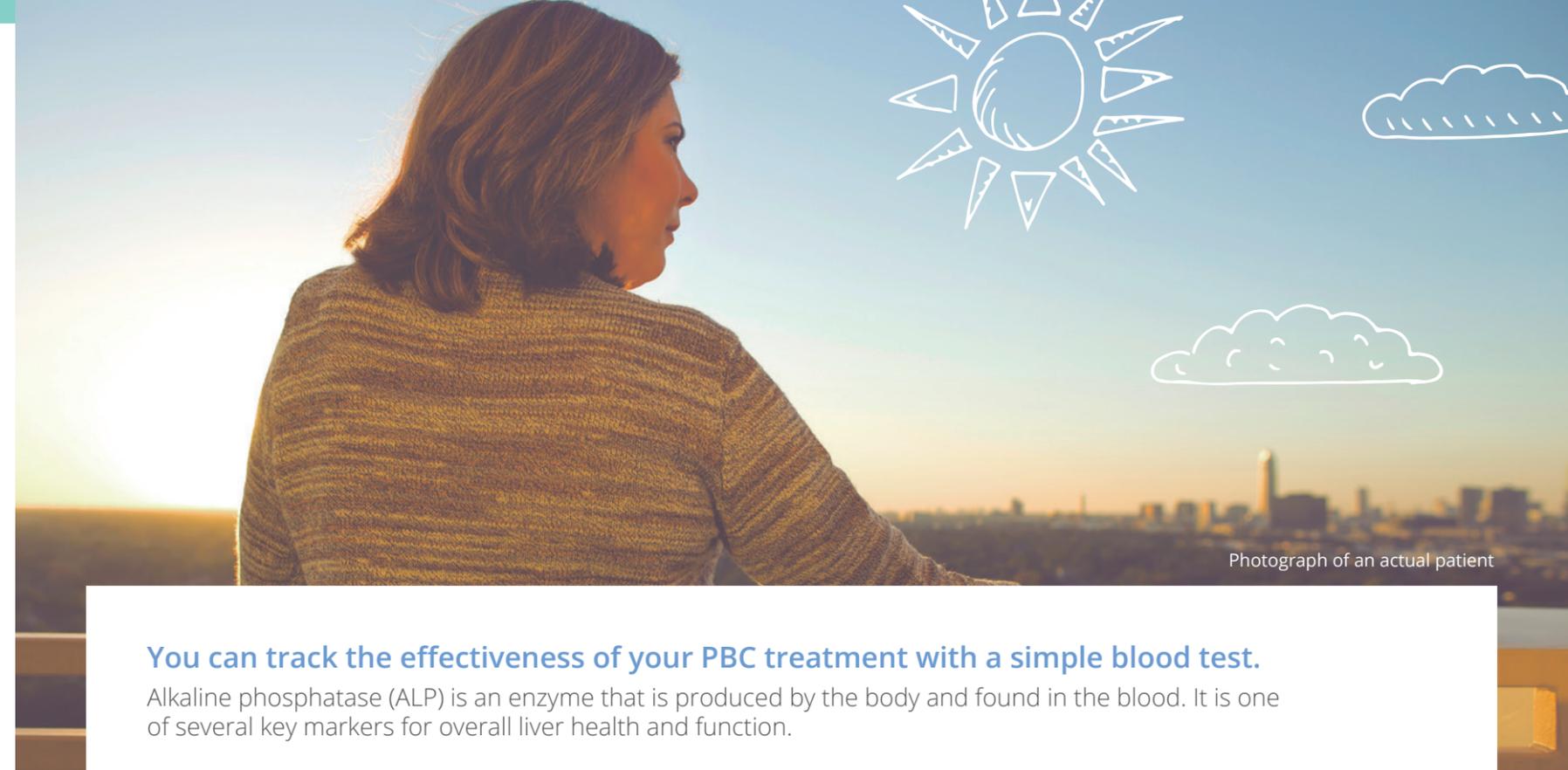
- ✓ Ask if there are any prescription or over-the-counter medications or products that may help with pruritus.
- ✓ Ask about prescription medications to help with fatigue, especially if you feel very sleepy during the day.
- ✓ Ask your healthcare team if there are any foods, types of exercise, or other lifestyle changes that may help.

IMPORTANT SAFETY INFORMATION

Who should not take OCALIVA?

Do not take OCALIVA if you have or had a complete blockage in the bile ducts in your liver or gallbladder.

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 or visit ocaliva.com.



Photograph of an actual patient

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

Alkaline phosphatase (ALP) is an enzyme that is produced by the body and found in the blood. It is one of several key markers for overall liver health and function.



ALP can be measured using a simple blood test.



When the ALP level is higher than normal, it can be a sign of liver damage.



Lowering your ALP level may reduce your risk of needing a liver transplant.

Medical guidelines recommend that you get a blood test to have your ALP level and other liver health marker levels checked every 3 to 6 months.

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



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

General PBC treatment goals include:

- ✓ Lower ALP levels
- ✓ Keep bilirubin levels within normal range

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

Because there is no cure, PBC treatment is a lifelong commitment—ongoing treatment is needed.

- Ursodeoxycholic acid (UDCA) is the most common treatment for people with any stage of PBC.
- Some people with PBC are unable to tolerate UDCA and require a different treatment option.
- In addition, up to 40% of people with PBC will be “nonresponders” to treatment with UDCA, which means blood tests show they still have certain liver health markers that could be further improved.^a

6

^aBased on Lammers et al, 2014, which states that up to 40% of people with PBC who are currently taking UDCA have an insufficient response and, accordingly, have a significantly increased risk of developing an adverse outcome, such as liver transplantation or death. This assessment is based on results from a group of global studies.

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

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 17.

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 or visit ocaliva.com.



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

OCALIVA does not interfere with how UDCA works, so the 2 medicines can be taken together.

For people who are unable to tolerate UDCA, OCALIVA can be taken alone.



Adding OCALIVA may positively affect key liver health markers by lowering ALP and keeping bilirubin levels stable.

In studies, almost half of people who took OCALIVA for a year were considered “responders” to treatment.

Most people in these studies took OCALIVA in combination with UDCA. People were considered “responders” if they:

- ✓ Had ALP levels less than 1.67 times the upper limit of normal^a
- ✓ Saw their ALP levels decrease by at least 15%
- ✓ Kept their bilirubin^b levels within the normal range

Taking OCALIVA can lower your ALP level even further.

 In a clinical study, people taking OCALIVA saw a reduction in ALP levels as early as 2 weeks after starting treatment.

Tip: Write down your ALP level before and after you start OCALIVA. Talk to your healthcare team about your progress.



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.

^aMany 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.

^bBilirubin 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.

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

PBC causes bile acid buildup, which can damage your liver.

PBC causes a person’s immune system to attack the bile ducts, creating scarring and inflammation, which traps toxic bile acids in the liver.

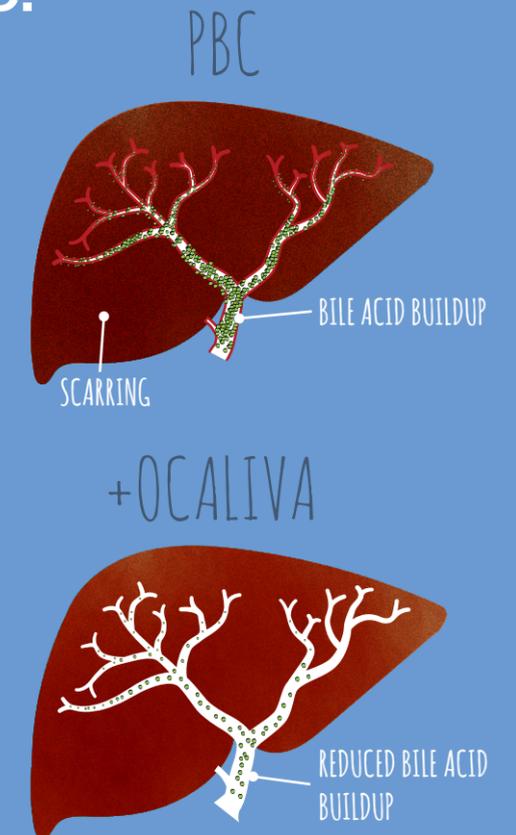
OCALIVA works to reduce toxic bile acid buildup caused by PBC in 2 key ways:

1. Reducing bile acid production
2. Increasing the flow of bile acids within the liver

ALP ↓

Adding OCALIVA to your current treatment plan can help.

By reducing bile acid buildup, OCALIVA may lower your ALP level.



Talk to your healthcare team about how OCALIVA can fit into your treatment plan.

IMPORTANT SAFETY INFORMATION

What are the possible side effects of OCALIVA?

OCALIVA may cause serious side effects including:

- **Severe Itching.** Itching (pruritus) is a common side effect and can sometimes become severe (intense itching or itching all over 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.

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 or visit ocaliva.com.


OCALIVA®
obeticholic acid

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.

IMPORTANT SAFETY INFORMATION

What are the possible side effects of OCALIVA?

OCALIVA may cause serious side effects including:

- **Decreases in Good Cholesterol.** Decreases in HDL-C (“good cholesterol”) have been observed in patients taking OCALIVA. Your healthcare provider will check your cholesterol levels during treatment to see if you should 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 or visit ocaliva.com.



OCALIVA may be working to lower your ALP level even if you are having symptoms.

If you experience itching, fatigue, or any other symptom or side effect while taking OCALIVA, talk to your healthcare team. Ask these important questions:

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 is important to take OCALIVA exactly as prescribed by your healthcare provider.



OCALIVA is a prescription oral medication for adults with PBC who still have elevated ALP levels while taking UDCA or cannot tolerate UDCA.

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.

If you tolerate OCALIVA well and your healthcare provider thinks you could further lower your ALP level, he or she may increase your dose **from 5 mg to 10 mg** after 3 months or more of treatment.

IMPORTANT SAFETY INFORMATION

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

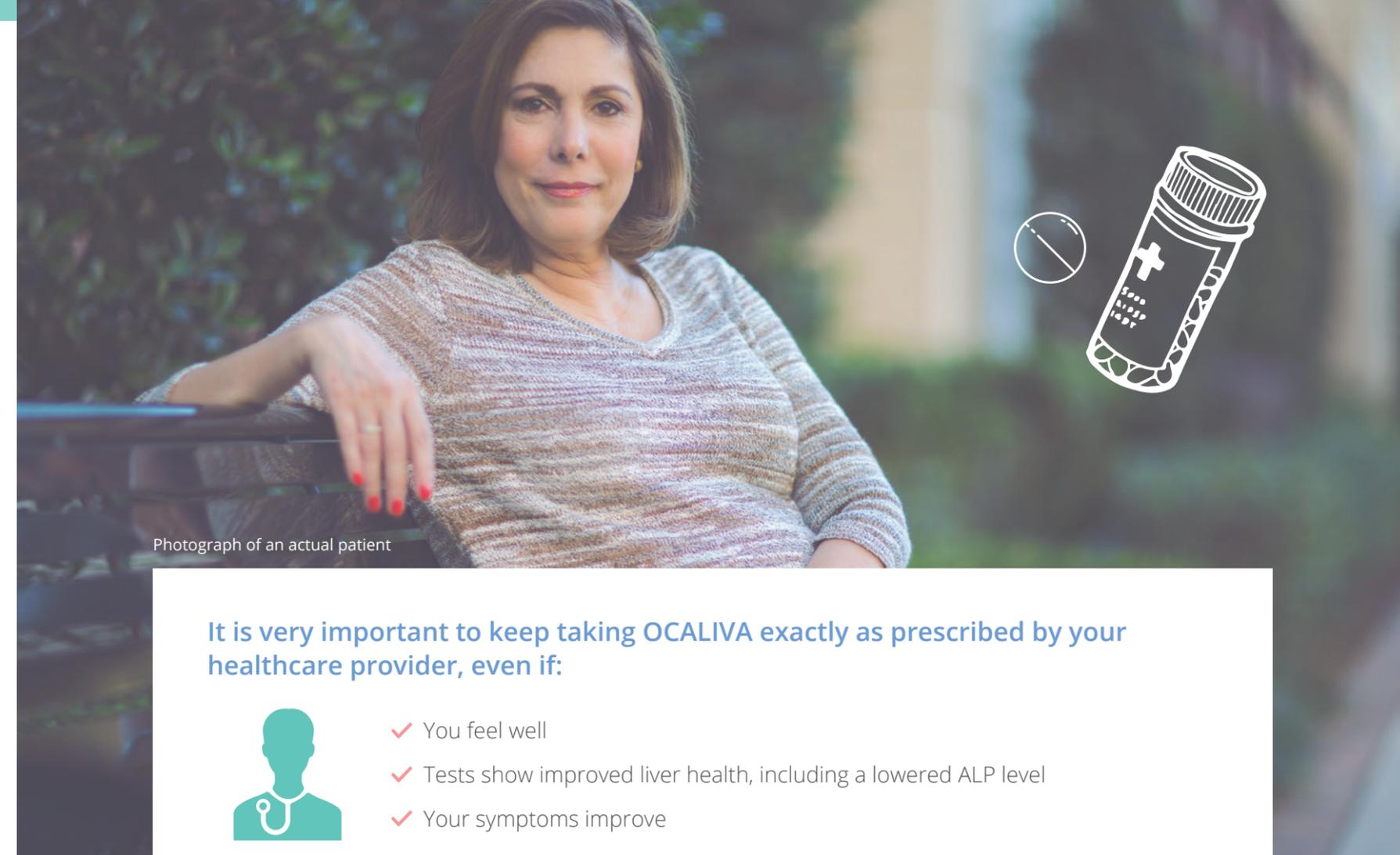
OCALIVA may cause serious side effects including:

Worsening of liver problems, 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.

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.

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"; or mental changes (such as confusion, sleepier than usual or harder to wake up, slurred speech, mood swings, or changes in personality)



It is very important to keep taking OCALIVA exactly as prescribed by your healthcare provider, even if:



- ✓ You feel well
- ✓ Tests show improved liver health, including a lowered ALP level
- ✓ Your symptoms improve

Remember, lifelong treatment for PBC is needed to keep ALP levels lowered and bilirubin levels stable, and to prevent liver damage.

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, or chills; light-headedness; less frequent urination

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 or visit ocaliva.com.





14

IMPORTANT SAFETY INFORMATION

What are the possible side effects of OCALIVA?

The most common side effects of OCALIVA include: pruritus (itching of the skin), 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, 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.

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 or visit ocaliva.com.

Interconnect[®] is here to help you start and stay on OCALIVA.

Interconnect[®]
SUPPORT SERVICES



Your dedicated Care Coordinator will help you with:



Financial assistance

We'll help you understand your current benefits and explore other financial assistance options, including a program that can help you get OCALIVA **for as little as a \$0 co-pay.**^a



Personalized support

We'll be in touch along the way to help you stay on track and 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.

Visit interconnectsupport.com to learn more.

^a 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

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. There are ongoing studies to find out how OCALIVA works over a longer period of time.

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, 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.

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.

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”; or 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, or chills; light-headedness; less frequent urination

Who should not take OCALIVA?

Do not take OCALIVA if you have or had a complete blockage in 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.** Itching (pruritus) is a common side effect and can sometimes become severe (intense itching or itching all over 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.
- **Decreases in Good Cholesterol.** Decreases in HDL-C (“good cholesterol”) have been observed in patients taking OCALIVA. Your healthcare provider will check your cholesterol levels during treatment to see if you should continue taking OCALIVA.

The most common side effects of OCALIVA include: pruritus (itching of the skin), 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, 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.

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.

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 or visit ocaliva.com. Rx only.

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

Photograph of an actual patient

EXPLORE YOUR WORLD OF PBC TREATMENT

Visit ocaliva.com

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 or visit ocaliva.com.

OCALIVA, Interconnect, and their respective logos, as well as the Intercept logo, are registered trademarks of Intercept Pharmaceuticals, Inc.
© 2020 Intercept Pharmaceuticals, Inc. All rights reserved. US-PP-PB-1162 01/20

Intercept 