



# Pruritus Action Plan

Information to help proactively manage this common primary biliary cholangitis (PBC) symptom and OCALIVA side effect

## 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 throughout and on pages 6 and 7 and click here for **Medication Guide** and **Full Prescribing Information**, including **Boxed WARNING**, for OCALIVA 5 mg and 10 mg tablets.

## What is pruritus?

Pruritus is itching of the skin. It affects most people with primary biliary cholangitis (PBC), even if they do not have a rash or other skin conditions.



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

If pruritus becomes severe enough, it can cause discomfort, disrupt sleep, and affect daily activities. **Itching sensations can also fluctuate**, and the severity of itching may reduce or even vanish completely over time. Making small changes in your daily routine, including the tips outlined in this brochure, can go a long way in helping you feel more comfortable.

### 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.

## What to expect when starting treatment

Pruritus is a common symptom of PBC and can also be a side effect of taking OCALIVA—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<sup>a</sup>** vs 10% of people who started on 10 mg; no patients in the placebo group discontinued

<sup>a</sup>193 of 198 patients continued treatment.

**97%**

**97% of people who completed the study chose to continue taking OCALIVA** in a long-term follow-up study



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# Tips to help manage pruritus

## Sleep

- **Practice good sleep habits.** Since itching can be worse at night, pruritus can cause you to lose sleep. Practicing good sleep habits and strategies can help you sleep longer and more soundly
  - **Play “white noise”** in the bedroom
  - **Use aromatherapy and massage**
  - **Maintain a cooler room temperature** at night
  - **Consider wearing gloves to bed**, so you don’t hurt yourself if you scratch an itch

## Hygiene

- **Take cool showers**
- **Apply a daily moisturizer**, such as Eucerin®
- **Keep fingernails trimmed** to avoid scratching yourself too hard
- **Switch to mild or clear/unscented soaps** and laundry detergents

## Over-the-counter treatments

- **Apply corticosteroid creams**, such as hydrocortisone
- **Take an antihistamine<sup>a</sup>**
- **Try capsaicin (hot pepper) cream**

<sup>a</sup>Recommended per the [Full Prescribing Information](#) for OCALIVA.



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**Taking proactive steps is important.** Even if you’re not currently experiencing itching, you can still avoid situations that could cause your skin to itch. Discuss with your HCP incorporating some of the suggestions below into your daily routine. Remember that every person is different, so it’s important to find a plan that works for you.  
This information is not intended to be medical advice. Always use products per instructions on label. Intercept® does not endorse any specific brand names for products.

## General

- **Stay hydrated** by drinking enough water
- **Wear loose-fitting clothes**
- **Try relaxation techniques**, such as meditation or aromatherapy
- **Use cold packs** or fabric strips soaked in cold water



**Staying away from the following can also help manage itching:**

## Diet (avoid)

- Hot and spicy foods

## General (avoid)

- Contact with allergenic and irritating substances, such as fragrances
- Activities and situations that contribute to dry skin (for example, saunas and dry climates)
- Overexcitement and stress
- Clothing made from fabrics that can irritate the skin, such as wool
- Smoking tobacco

## 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

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**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:**

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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.

### 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 Medication Guide and Full Prescribing Information 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  
an actual patient.

## Connect With Others Living With PBC

The **OCALIVA Connect Mentor Program** connects you with an OCALIVA mentor—a real patient ambassador living with PBC—so you can get helpful insights on managing pruritus and other side effects, working with your healthcare team, and more.

**Call to schedule a session today:  
1-833-508-9362**

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

**Interconnect can help you start and stay on therapy**

To connect with a Care Coordinator, **call 1-844-622-4278.**

For more information, **visit [interconnectsupport.com](https://interconnectsupport.com)**

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obeticholic acid

**Intercept** 