

## Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

▼ This medicine is new or being used differently. Please report side effects. See the [full CMI](#) for further details.

**WARNING:** Important safety information is provided in a boxed warning in the [full CMI](#). Read before using this medicine.

### 1. Why am I using OCALIVA?

OCALIVA contains the active ingredient obeticholic acid. OCALIVA is used to treat adults with a type of liver disease known as primary biliary cholangitis (PBC). It is used either by itself or with another medicine called ursodeoxycholic acid.

For more information, see Section [1. Why am I using OCALIVA?](#) in the full CMI.

### 2. What should I know before I use OCALIVA?

Do not use if you have ever had an allergic reaction to obeticholic acid or any of the ingredients listed at the end of the CMI.

Do not use if you have or have had severe liver-related problems such as fluid in the belly, yellowing of the skin and/or eyes, or confusion (decompensated liver cirrhosis); you have bleeding in the digestive system, bleed or bruise more easily, or have been told you have low platelets in your blood (compensated cirrhosis with increased blood pressure in your abdomen); or you have a complete blockage in your liver or gallbladder.

**Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.**

For more information, see Section [2. What should I know before I use OCALIVA?](#) in the full CMI.

### 3. What if I am taking other medicines?

Some medicines may interfere with OCALIVA and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

### 4. How do I use OCALIVA?

- Take one 5 mg tablet once daily for 6 months.
- Depending on your response, your doctor may increase your dose to 10 mg once daily.

More instructions can be found in Section [4. How do I use OCALIVA?](#) in the full CMI.

### 5. What should I know while using OCALIVA?

<b>Things you should do</b>	<ul style="list-style-type: none"><li>• Remind any doctor, dentist or pharmacist you visit that you are using OCALIVA.</li><li>• Keep all of your doctor appointments so that your progress can be checked. Your doctor will do some tests to make sure the medicine is working and to prevent unwanted side effects.</li><li>• Call your doctor straight away if you have worsening liver problems or any other serious illness.</li></ul>
<b>Things you should not do</b>	<ul style="list-style-type: none"><li>• Do not stop using this medicine suddenly or change the amount you take or take it for any other complaints without speaking to your doctor first.</li></ul>
<b>Driving or using machines</b>	<ul style="list-style-type: none"><li>• Be careful before you drive or use any machines or tools until you know how OCALIVA affects you.</li><li>• OCALIVA is not expected to affect your ability to drive a car or operate machinery.</li></ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"><li>• Store the bottle where the temperature stays below 25°C.</li></ul>

For more information, see Section [5. What should I know while using OCALIVA?](#) in the full CMI.

### 6. Are there any side effects?

All medicines can have side effects. Most of them are minor and temporary, although some may need medical attention.

Very common side effects may include: feeling tired and itchy skin (particularly when first starting OCALIVA), and stomach pain and discomfort.

Serious side effects may include: allergic reactions and worsening of liver problems (such as yellowing of eyes or skin; bruising or bleeding easily; vomiting blood, swelling of your stomach-area; confusion; and loss of appetite or weight loss).

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

This medicine is subject to additional monitoring in Australia. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. You can report side effects to your doctor, or directly at [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems).

## WARNING

- Worsening of liver problems and liver failure in some cases leading to liver transplant or death has happened in some people with PBC with liver cirrhosis when taking OCALIVA
- Your doctor will check your liver before you take OCALIVA and while you are taking it. These liver tests will help your doctor decide if it is safe for you to start and continue taking OCALIVA.
- Do not use OCALIVA if you have or ever have had severe liver-related problems such as fluid in the belly, yellowing of the skin and/or eyes, or confusion (decompensated liver cirrhosis) or you have bleeding in the digestive system, bleed or bruise more easily, or have been told you have low platelets in your blood (compensated cirrhosis with increased blood pressure in your abdomen).
- You should stop taking OCALIVA and see your doctor immediately if you experience the above symptoms or have a complete blockage of the biliary tract (liver, gall bladder and bile ducts) or have worsening liver problems.

# OCALIVA®

Active ingredient: *obeticholic acid*

## Consumer Medicine Information (CMI)

This leaflet provides important information about using OCALIVA. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using OCALIVA.**

Where to find information in this leaflet:

1. [Why am I using OCALIVA?](#)
2. [What should I know before I use OCALIVA?](#)
3. [What if I am taking other medicines?](#)
4. [How do I use OCALIVA?](#)
5. [What should I know while using OCALIVA?](#)
6. [Are there any side effects?](#)
7. [Product details](#)

## 1. Why am I using OCALIVA?

**OCALIVA contains the active ingredient obeticholic acid.**

OCALIVA is a “farnesoid X-receptor agonist” which helps to improve how your liver works by reducing the production and build-up of bile in the liver and by reducing inflammation.

OCALIVA is used to treat adults with a type of liver disease known as primary biliary cholangitis (PBC). It is used either by itself or with another medicine called ursodeoxycholic acid.

## 2. What should I know before I use OCALIVA?

### Warnings

**Do not use OCALIVA if:**

- you are allergic to obeticholic acid, or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can use this medicine.

- you have or ever have had severe liver-related problems such as fluid in the belly, yellowing of the skin and/or eyes, or confusion (decompensated liver cirrhosis)
- you have bleeding in the digestive system, bleed or bruise more easily, or have been told you have low platelets in your blood (compensated cirrhosis with increased blood pressure in your abdomen)
- you have a complete blockage of the biliary tract (liver, gall bladder and bile ducts).

**Check with your doctor if you:**

- have any other medical conditions
- take any medicines for any other condition.

Your doctor will do tests to check your liver before you start OCALIVA. These tests will help your doctor decide if it is safe for you to start taking OCALIVA. You will also have regular tests while you are taking OCALIVA to check your progress.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

### Pregnancy and breastfeeding

**Check with your doctor if you are pregnant or intend to become pregnant.**

Your doctor can discuss with you the risks and benefits involved.

There is little information about the effects of OCALIVA in pregnancy. As a precautionary measure, you should not take OCALIVA if you are pregnant.

**Talk to your doctor if you are breastfeeding or intend to breastfeed.**

It is not known if this medicine passes into human milk.

Your doctor will decide whether you should stop breast-feeding or not take OCALIVA, by taking into account the benefit of breast feeding for the child and the benefit of therapy for you.

### Children and adolescents

Do not give this medicine to a child or adolescent under the age of 18 years.

## 3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

**Some medicines may interfere with OCALIVA and affect how it works.**

These include:

- bile acid binding resins (cholestyramine, colestipol, colesevelam) used to lower blood cholesterol levels as they may lessen the effect of OCALIVA. If you take any of these medicines, take OCALIVA at least 4-6 hours before or 4-6 hours after taking bile acid binding resin, giving as much time as possible.
- theophylline (a medicine to help breathing) as levels of this medicine may be increased and will need to be monitored by your doctor while taking OCALIVA.
- warfarin (a medicine to help your blood flow) as levels of this medicine may be increased. Your doctor may need to monitor how well your blood clots when taking medicines such as warfarin with OCALIVA.
- cyclosporin (a medicine to prevent rejection of organ transplants and treat problems with the immune system). If it must be taken with OCALIVA then you may have extra tests to monitor your liver.

**Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect OCALIVA.**

## 4. How do I use OCALIVA?

### How much to take

- Take one 5 mg tablet once daily for 6 months. Depending on your response, your doctor may increase your dose to 10 mg once daily.
- Swallow the tablet whole with a full glass of water.
- Follow the instructions provided and use OCALIVA until your doctor tells you to stop.
- If you have worsening liver problems or a side effect such as severe itching, your doctor may decrease the dose, give you a break from taking it or tell you to stop taking it.

### When to take OCALIVA

- OCALIVA should be taken at the same time each day.
- It does not matter if you take this medicine before or after food.
- If you take bile acid binding resins, take this medicine at least 4-6 hours before or after the bile acid binding resin (see Section [3. What if I am taking other medicines?](#)).

### If you forget to use OCALIVA

OCALIVA should be used regularly at the same time each day. If you miss your dose at the usual time, skip the dose you missed and take your next dose when you would normally take it.

**Do not take a double dose to make up for the dose you missed.**

### If you use too much OCALIVA

If you think that you have used too much OCALIVA, you may need urgent medical attention.

**You should immediately:**

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

**You should do this even if there are no signs of discomfort or poisoning.**

## 5. What should I know while using OCALIVA?

### Things you should do

Keep all of your doctor appointments so that your progress can be checked.

Your doctor will do some tests from time to time to make sure the medicine is working and to prevent unwanted side effects.

**Call your doctor straight away if you have any of the following signs of worsening liver problems:**

- 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, feeling sleepier than usual or harder to wake up, slurred speech, mood swings or changes in personality.

Worsening of liver problems and liver failure in some cases leading to liver transplant or death has happened in people with PBC with liver cirrhosis when taking OCALIVA (see also Section [6. Are there any side effects?](#)).

**Talk to your doctor or pharmacist if you experience itching of the skin (pruritus) or an increase in the severity of itching while taking OCALIVA.**

Itching of the skin is a very common side effect that usually begins within the first month of treatment and decreases in severity over time. Your doctor may prescribe other medicines for treatment of itching, adjust your dose of OCALIVA or recommend other things you can do to relieve the itching.

**Talk to your doctor or pharmacist if you feel tired (fatigue) and it worries you.**

Fatigue is a very common side effect and your doctor may recommend things that might help you.

**Remind any doctor, dentist or pharmacist you visit that you are using OCALIVA.**

### Things you should not do

- Do not stop taking your medicine or lower the dosage without checking with your doctor
- Do not take OCALIVA to treat any other complaints unless your doctor tells you to.
- Do not give your medicine to anyone else, even if they have the same condition as you.

### Driving or using machines

**Be careful before you drive or use any machines or tools until you know how OCALIVA affects you.**

OCALIVA is not expected to affect your ability to drive a car or operate machinery.

### Looking after your medicine

- Keep the tablets in the bottle until it is time to take them. If you take the tablets out of the bottle they may not keep as well.
- Store the bottle where the temperature stays below 25°C.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

**Keep it where young children cannot reach it.**

### Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

## 6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

### Less serious side effects

Less serious side effects	What to do
<p><b>Digestive system:</b></p> <ul style="list-style-type: none"> <li>• stomach pain or discomfort</li> <li>• constipation</li> </ul> <p><b>Ear, nose, throat and mouth:</b></p> <ul style="list-style-type: none"> <li>• sore mouth and throat</li> </ul> <p><b>General body:</b></p> <ul style="list-style-type: none"> <li>• feeling tired</li> <li>• swelling in the hands and feet</li> <li>• fever</li> </ul> <p><b>Heart:</b></p> <ul style="list-style-type: none"> <li>• fast or irregular heartbeat (palpitations)</li> </ul> <p><b>Hormones:</b></p> <ul style="list-style-type: none"> <li>• changes in how your thyroid gland works</li> </ul> <p><b>Muscles and bones:</b></p> <ul style="list-style-type: none"> <li>• joint pain</li> </ul> <p><b>Nervous system:</b></p> <ul style="list-style-type: none"> <li>• feeling dizzy</li> </ul> <p><b>Skin:</b></p> <ul style="list-style-type: none"> <li>• itchy skin</li> <li>• red, dry and inflamed skin (eczema)</li> <li>• rash</li> </ul> <p><b>Tests requested by your doctor:</b></p> <ul style="list-style-type: none"> <li>• increase in bilirubin and liver enzymes</li> <li>• time taken for your blood to clot</li> <li>• lower levels of HDL-C ("good" cholesterol)</li> </ul>	<p><b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b></p>

### Serious side effects

Serious side effects	What to do
<p><b>Hypersensitivity (allergic) reaction:</b></p> <ul style="list-style-type: none"> <li>• may include rash, itching or hives on the skin; shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body</li> </ul> <p><b>Liver-related problems:</b></p> <ul style="list-style-type: none"> <li>• yellowing of eyes or skin (jaundice)</li> <li>• bruising or bleeding easily, vomiting blood, swelling of your stomach-area from a build-up of fluid (may be a sign of liver failure)</li> <li>• weakness, tiredness, loss of appetite, weight loss, stomach pain, nausea, vomiting, ankle swelling (may be sign of scarring of the liver known as cirrhosis)</li> </ul>	<p><b>Call your doctor straight away or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</b></p>

**Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.**

Other side effects not listed here may occur in some people.

### **Reporting side effects**

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems). By reporting side effects, you can help provide more information on the safety of this medicine.

**Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.**

## **7. Product details**

This medicine is only available with a doctor's prescription.

### **What OCALIVA contains**

<b>Active ingredient (main ingredient)</b>	<ul style="list-style-type: none"><li>• obeticholic acid</li></ul>
<b>Other ingredients (inactive ingredients)</b>	<ul style="list-style-type: none"><li>• microcrystalline cellulose</li><li>• sodium starch glycolate type A</li><li>• magnesium stearate</li><li>• Opadry II complete film coating system 85F32351 YELLOW</li></ul>

**Do not take this medicine if you are allergic to any of these ingredients.**

### **What OCALIVA looks like**

OCALIVA 5 mg is a yellow, round film-coated tablet with 'INT' on one side and '5' on the other side (AUST R 293379).

OCALIVA 10 mg is a yellow, triangular film-coated tablet with 'INT' on one side and '10' on the other side (AUST R 293378).

The tablets are packed in a plastic high-density polyethylene (HDPE) bottle with a child resistant polypropylene closure and an aluminium foil seal.

Bottles contain 30 tablets or 100\* tablets.

\*Pack size is not currently available.

### **Who supplies OCALIVA**

Amdipharm Mercury (Australia) Pty Ltd  
Level 9, 76 Berry Street  
North Sydney NSW 2060  
Ph: 1800 627 680

Amdipharm Mercury (Australia) Pty Ltd is an ADVANZ PHARMA company

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