



This medicine is subject to additional monitoring. 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.

OCALIVA®

Obeticholic acid

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about OCALIVA. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking OCALIVA against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What OCALIVA is used for

OCALIVA contains the active substance obeticholic acid (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 also reducing inflammation.

This medicine is used to treat adult patients with a type of liver disease known as primary biliary cholangitis (PBC), either by itself or together with another medicine, ursodeoxycholic acid.

Ask your doctor if you have any questions about why this

medicine has been prescribed for you.

Your doctor may have prescribed it for another reason.

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

Before you take OCALIVA

When you must not take it

Do not take 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)
- if you have a complete blockage of the biliary tract (liver, gall bladder and bile ducts).

Do not take OCALIVA if you have an allergy to:

- any medicine containing obeticholic acid
- any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin.

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

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If the medicine has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start taking this medicine, talk to your doctor.

Before you start to take it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Before you start OCALIVA, and during your treatment with OCALIVA, your doctor will do tests to check your liver. These tests will help your doctor decide if it is safe for you to start taking OCALIVA and safe for you to continue taking OCALIVA.

If you have worsening liver problems, your dose of OCALIVA may be stopped for a period of time or stopped completely by your doctor.

Worsening of liver problems, liver failure, in some cases leading to liver transplant or death, has happened in people with PBC with liver cirrhosis when taking OCALIVA.

Tell your doctor 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 doctor if you are pregnant or plan to become pregnant or are breast-feeding.

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.

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

Your doctor will determine whether you should discontinue breast-feeding or discontinue/abstain from OCALIVA therapy taking into account the benefit of breast-feeding for the child and the benefit of therapy for you.

If you have not told your doctor about any of the above, tell him/her before you start taking OCALIVA.

Taking other medicines

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

Some medicines and OCALIVA may interfere with each other.

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.

These medicines may be affected by OCALIVA or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking OCALIVA.

How to take OCALIVA

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the bottle, ask your doctor or pharmacist for help.

How much to take

Your doctor will advise you of the dose to take and discuss any change of dose with you. Talk to your doctor or pharmacist if you are unsure.

The recommended dose is one 5 mg tablet once daily by mouth.

Depending on your body's response after 6 months your doctor may increase your dose to 10 mg once daily.

How to take it

Swallow the tablet whole with a full glass of water.

When to take it

Take your medicine at about the same time each day.

Taking it at the same time each day will have the best effect. It will also help you remember when to take it.

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 at least 4-6 hours after the bile acid binding resin (see section "Taking other medicines").

How long to take it

You should continue to take OCALIVA for as long as your doctor tells you to.

Do not stop taking the medicine without talking to your doctor first.

If you forget to take it

Skip the missed dose and take your next dose when you would normally take it.

Do not take a double dose to make up for a forgotten tablet.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

If you take too much (overdose)

If you accidentally take too many tablets, you may experience liver-related side effects such as yellowing of the skin.

Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26) for advice, or go to Accident and

Emergency at the nearest hospital, if you think that you or anyone else may have taken too much OCALIVA. Do this even if there are no signs of discomfort or poisoning.

While you are using OCALIVA

Things you must do

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking OCALIVA.

Tell any other doctors, dentists, and pharmacists who treat you that you are taking this medicine.

If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine.
It may affect other medicines used during surgery.

If you become pregnant while taking this medicine, tell your doctor immediately.

Your doctor will do blood tests to monitor the health of your liver when you start treatment and regularly from there on.

If you are going to have any blood tests, tell your doctor that you are taking this medicine.

It may interfere with the results of some tests.

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

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

Things you must not do

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.

Do not stop taking your medicine or lower the dosage without checking with your doctor.

If you stop taking OCALIVA suddenly, your condition may worsen or you may have unwanted side effects.

Things to be careful of

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

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking OCALIVA.

This medicine helps most people with primary biliary cholangitis, but it may have unwanted side effects in a few people.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor or pharmacist if you experience itching of the skin (pruritus) or an increase in the severity of itching while on this medicine.

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

Tell 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.

OCALIVA can lower high levels of HDL-C (“good” cholesterol). Your doctor will check your cholesterol levels during your treatment with OCALIVA.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- stomach pain or discomfort
- thyroid hormone irregularity
- dizziness
- fast or irregular heart beat (palpitations)
- pain in the mouth and throat
- constipation
- dry skin, redness of the skin (eczema)
- rash
- pain in your joints
- swelling in the hands and feet
- fever.

The above list includes the more common side effects of your medicine.

The following side effects have been reported since the marketing of OCALIVA, but how often they occur is not known. If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- bruising or bleeding easily, vomiting blood, swelling of your stomach-area from a build-up of fluid (liver failure)
- increase in bilirubin (a substance produced by the liver) in the blood
- yellowing of eyes or skin (jaundice)
- weakness, tiredness, loss of appetite, weight loss, stomach pain, nausea, vomiting, ankle swelling (scarring of the liver known as cirrhosis).

Some of these side effects (for example, increase in bilirubin) can only be found when your doctor does liver function tests.

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation.

Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

Other side effects not listed above may also occur in some people.

After using OCALIVA

Storage

Keep your tablets in the bottle until it is time to take them.

If you take the tablets out of the bottle they may not keep well.

Keep your tablets in a cool, dry place where the temperature stays below 25°C.

Do not store OCALIVA or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car.

Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Product description

What it looks like

OCALIVA 5 mg is a yellow, round film-coated tablet with 'INT' on one side and '5' on the other side of the film-coated tablet.

OCALIVA 10 mg is a yellow, triangular film-coated tablet with 'INT' on one side and '10' on the other side of the film-coated tablet.

Ingredients

The active substance is obeticholic acid.

OCALIVA 5 mg film-coated tablets contain 5 mg of obeticholic acid.

OCALIVA 10 mg film-coated tablets contain 10 mg of obeticholic acid.

The other ingredients are:

- microcrystalline cellulose
- sodium starch glycollate type A
- magnesium stearate
- Opadry II complete film coating system 85F32351 YELLOW.

Supplier

OCALIVA is supplied in Australia by:

Chiesi Australia Pty Ltd
Suite 3, 22 Gillman Street
Hawthorn East, VIC 3123

Email:
medicalaffairs.au@chiesi.com
Website: www.chiesi.com.au

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AUST R 293379 (5 mg)

AUST R 293378 (10 mg)