Source : Medicines Org UK

OCALIVA 5 mg film-coated tablets OCALIVA 10 mg film-coated tablets
obeticholic acid

▼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. See the end of section 4 for how to report side effects.

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What OCALIVA is and what it 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 (also known as primary biliary cirrhosis), either by itself or together with another medicine, ursodeoxycholic acid.

2. What you need to know before you take OCALIVA

Do not take OCALIVA:
- if you are allergic to obeticholic acid or any of the other ingredients of this medicine (listed in section 6).
- if you have a complete blockage of the biliary tract (liver, gall bladder and bile ducts).

Warnings and precautions
Talk to your doctor or pharmacist before taking OCALIVA.

If you experience itching that is difficult to tolerate, talk to your doctor.

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

Children and adolescents
This medicine is not for use in children or adolescents.

Other medicines and OCALIVA
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

In particular, tell your doctor if you are taking so-called 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.

The levels of some medicines such as theophylline (a medicine to help breathing) or tizanidine (a medicine to relieve the stiffness and restriction of muscles) may be increased and need to be monitored by your doctor while taking OCALIVA. Your doctor may need to monitor how well your blood clots when taking medicines such as warfarin (a medicine to help your blood flow) with OCALIVA.

Pregnancy and breast-feeding
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.

Driving and using machines
This medicine has no or negligible influence on your ability to drive or use machines.

3. How to take OCALIVA

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose is one 5 mg film-coated tablet once daily by mouth.
Your doctor may adjust your dose depending on your liver function or if you experience itching that is difficult to tolerate.

Depending on your body's response after 6 months your doctor may increase your dose to 10 mg once daily. Your doctor will discuss any change of dose with you.

You can take OCALIVA with or without 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 "Other medicines and OCALIVA").

If you take more OCALIVA than you should
If you accidentally take too many tablets, you may experience liver related side effects such as yellowing of the skin. Contact a doctor or go to a hospital for advice immediately.

If you forget to take OCALIVA
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 stop taking OCALIVA
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 have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Tell your doctor or pharmacist if you experience itching of the skin (pruritus) or if the itch gets worse 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 usually becomes less severe over time..

Very common side effects (may affect more than 1 in 10 people):
- stomach pain
- feeling tired

Common side effects (may affect up to 1 in 10 people):
- 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

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via Yellow Card Scheme Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.
By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store OCALIVA

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and bottle after "EXP". The expiry date refers to the last day of that month.

This medicinal product does not require any special storage conditions.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What OCALIVA contains
The active substance is obeticholic acid.
OCALIVA 5 mg film-coated tablets: Each film-coated tablet contains 5 mg of obeticholic acid.
OCALIVA 10 mg film-coated tablets: Each film-coated tablet contains 10 mg of obeticholic acid.

- The other ingredients are:
  - Tablet core: Microcrystalline cellulose (E460), sodium starch glycolate (Type A), magnesium stearate.
  - Film-coat: Polyvinyl alcohol, part hydrolysed (E1203), titanium dioxide (E171), macrogol 3350 (E1521), talc (E553b), iron oxide yellow (E172).

What OCALIVA looks like and contents of the pack

- 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.

Pack sizes
1 bottle with 30 or 100 film-coated tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder
Intercept Pharma Ltd.
2 Pancras Square
London, N1C 4AG
United Kingdom

Manufacturer
Almac Pharma Services
Seagoe Industrial Estate
Portadown
Craigavon
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For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder:

Intercept Pharma UK & Ireland Ltd.
Tel: + 44 330 100 3694

This leaflet was last revised in 03/2018.

This medicine has been given 'conditional approval'. This means that there is more evidence to come about this medicine.

The European Medicines Agency will review new information on this medicine at least every year and this leaflet will be updated as necessary.

Other sources of information

Detailed information on this medicine is available on the European Medicines Agency web site: http://www.ema.europa.eu. There are also links to other websites about rare diseases and treatments.