



PATIENT & CAREGIVER EDUCATION

Obeticholic Acid

This information from Lexicomp® explains what you need to know about this medication, including what it's used for, how to take it, its side effects, and when to call your healthcare provider.

Brand Names: US

Ocaliva [DSC]

Brand Names: Canada

Ocaliva

Warning

- Serious liver problems have happened with this drug. If you have ever had liver problems, talk with your doctor. This drug may not be right for people with some types of liver cirrhosis. Worsening of liver problems has happened in these people. Sometimes, this has led to a liver transplant or been deadly. Call your doctor right away if you have signs of liver problems like dark urine; feeling tired or weak; decreased appetite; upset stomach, stomach pain, or swelling in stomach area; light-colored stools; throwing up; yellow skin or eyes; black, tarry, or bloody stools; coughing up blood; throwing up blood or throw up that looks like coffee grounds; or mental or mood changes like confusion, feeling very sleepy, mood swings, or change in behavior. Call your doctor right away if you have any of these effects and they are severe or do not go away: diarrhea, fever, chills, weight loss, feeling lightheaded, or passing urine less often.

What is this drug used for?

- It is used to treat primary biliary cholangitis (PBC).

What do I need to tell my doctor BEFORE I take this drug?

- If you are allergic to this drug; any part of this drug; or any other drugs, foods, or substances. Tell your doctor about the allergy and what signs you had.
- If you have bile tract blockage.
- If you are taking cyclosporine.

This is not a list of all drugs or health problems that interact with this drug.

Tell your doctor and pharmacist about all of your drugs (prescription or OTC, natural products, vitamins) and health problems. You must check to make sure that it is safe for you to take this drug with all of your drugs and health problems. Do not start, stop, or change the dose of any drug without checking with your doctor.

What are some things I need to know or do while I take this drug?

- Tell all of your health care providers that you take this drug. This includes your doctors, nurses, pharmacists, and dentists.
- Have blood work checked as you have been told by the doctor. Talk with the doctor.
- This drug can lower good cholesterol (HDL). If you have questions, talk with the doctor.

- Other drugs may be given with this drug to help avoid side effects.
- Tell your doctor if you are pregnant, plan on getting pregnant, or are breast-feeding. You will need to talk about the benefits and risks to you and the baby.

What are some side effects that I need to call my doctor about right away?

WARNING/CAUTION: Even though it may be rare, some people may have very bad and sometimes deadly side effects when taking a drug. Tell your doctor or get medical help right away if you have any of the following signs or symptoms that may be related to a very bad side effect:

- Signs of an allergic reaction, like rash; hives; itching; red, swollen, blistered, or peeling skin with or without fever; wheezing; tightness in the chest or throat; trouble breathing, swallowing, or talking; unusual hoarseness; or swelling of the mouth, face, lips, tongue, or throat.
- Signs of thyroid problems like change in weight; feeling nervous, excitable, restless, or weak; hair thinning; depression; eye or neck swelling; not able to focus; trouble with heat or cold; menstrual changes; shakiness; or sweating.
- Swelling in the arms or legs.

- Fast or abnormal heartbeat.

What are some other side effects of this drug?

All drugs may cause side effects. However, many people have no side effects or only have minor side effects. Call your doctor or get medical help if any of these side effects or any other side effects bother you or do not go away:

- Feeling dizzy, tired, or weak.
- Stomach pain.
- Joint pain.
- Mouth or throat pain or irritation.
- Constipation.
- Skin dryness, irritation, redness, crusting, or drainage (eczema).
- Itching is common with this drug. Severe itching can lead to pain, trouble sleeping, and problems with daily living. Call your doctor right away if you have itching that is severe, causes problems with daily living, or does not go away.

These are not all of the side effects that may occur. If you have questions about side effects, call your doctor. Call your doctor for medical advice about side effects.

You may report side effects to your national health

agency.

You may report side effects to the FDA at 1- 800-332-1088.

You may also report side effects at

<https://www.fda.gov/medwatch>.

How is this drug best taken?

Use this drug as ordered by your doctor. Read all information given to you. Follow all instructions closely.

- Take with or without food.
- Do not take colesevelam, colestipol, or cholestyramine within 4 hours before or 4 hours after taking this drug.

What do I do if I miss a dose?

- Take a missed dose as soon as you think about it.
- If it is close to the time for your next dose, skip the missed dose and go back to your normal time.
- Do not take 2 doses at the same time or extra doses.

How do I store and/or throw out this drug?

- Store at room temperature in a dry place. Do not store in a bathroom.
- Keep all drugs in a safe place. Keep all drugs out of the reach of children and pets.
- Throw away unused or expired drugs. Do not flush down

a toilet or pour down a drain unless you are told to do so. Check with your pharmacist if you have questions about the best way to throw out drugs. There may be drug take-back programs in your area.

General drug facts

- If your symptoms or health problems do not get better or if they become worse, call your doctor.
- Do not share your drugs with others and do not take anyone else's drugs.
- Some drugs may have another patient information leaflet. If you have any questions about this drug, please talk with your doctor, nurse, pharmacist, or other health care provider.
- This drug comes with an extra patient fact sheet called a Medication Guide. Read it with care. Read it again each time this drug is refilled. If you have any questions about this drug, please talk with the doctor, pharmacist, or other health care provider.
- If you think there has been an overdose, call your poison control center or get medical care right away. Be ready to tell or show what was taken, how much, and when it happened.

Consumer Information Use and Disclaimer

This generalized information is a limited summary of diagnosis, treatment, and/or medication information. It is not meant to be comprehensive and should be used as a tool to help the user understand and/or assess potential diagnostic and treatment options. It does NOT include all information about conditions, treatments, medications, side effects, or risks that may apply to a specific patient. It is not intended to be medical advice or a substitute for the medical advice, diagnosis, or treatment of a health care provider based on the health care provider's examination and assessment of a patient's specific and unique circumstances. Patients must speak with a health care provider for complete information about their health, medical questions, and treatment options, including any risks or benefits regarding use of medications. This information does not endorse any treatments or medications as safe, effective, or approved for treating a specific patient. UpToDate, Inc. and its affiliates disclaim any warranty or liability relating to this information or the use thereof. The use of this information is governed by the Terms of Use, available at <https://www.wolterskluwer.com/en/know/clinical-effectiveness-terms>.

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If you have questions or concerns, contact your healthcare provider. A member of your care team will answer Monday through Friday from 9 a.m. to 5 p.m. Outside those hours, you can leave a message or talk with another MSK provider. There is always a doctor or nurse on call. If you're not sure how to reach your healthcare provider, call 212-639-2000.

For more resources, visit www.mskcc.org/pe to search our virtual library.

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