



PATIENT & CAREGIVER EDUCATION

Elafibranor

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

Iqirvo

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 advanced or worsening liver disease.
- If you have bile duct blockage. Tell your doctor right away if you have signs of bile duct blockage like upper right stomach pain or yellow skin or eyes.
- If you are breast-feeding. Do not breast-feed while you

take this drug and for 3 weeks after your last dose.

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 your blood work and other lab tests checked as you have been told by your doctor.
- This drug may raise the chance of a broken bone. Talk with the doctor.
- If you are 75 or older, use this drug with care. You could have more side effects.
- This drug may cause harm to an unborn baby. A pregnancy test will be done before you start this drug to show that you are NOT pregnant.

- If you may become pregnant, you must use birth control while taking this drug and for some time after the last dose. Birth control pills and other hormone-based birth control may not work as well to prevent pregnancy while taking this drug. Talk with your doctor about what type of birth control to use and how long to use it. If you get pregnant, call your doctor right away.

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 worsening liver problems like dark urine; feeling tired or weak; feeling very sleepy or harder to wake up; confusion; slurred speech; mood changes;

stomach swelling; black, tarry, or bloody stools; coughing up or throwing up blood or throw up that looks like coffee grounds; light-colored stools; or yellow skin or eyes.

- Bone pain, change in being able to move around, or bone or joint that looks different.
- This drug may cause muscle pain, tenderness, or weakness. A severe muscle problem (rhabdomyolysis) leading to kidney problems may happen. Call your doctor right away if you have new or worsening muscle pain, tenderness, or weakness. Call your doctor right away if you have signs of kidney problems like dark, reddish urine or trouble passing urine.

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:

- Weight gain or loss.
- Constipation, diarrhea, stomach pain, upset stomach, throwing up, or decreased appetite.
- Joint pain.

- Dry mouth.

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.
- Keep taking this drug as you have been told by your doctor or other health care provider, even if you feel well.
- 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.
- Store in the original container to protect from light.
- 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

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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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