PATIENT & CAREGIVER EDUCATION

Odevixibat

This information from UpToDate® Lexidrug™ 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

Bylvay; Bylvay (Pellets)

Brand Names: Canada

Bylvay; Bylvay (Pellets)

What is this drug used for?

- It is used to treat itching in certain people with progressive familial intrahepatic cholestasis (PFIC).
- It is used to treat itching in people with Alagille syndrome (ALGS).

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 liver problems or have had severe effects caused by liver problems.

This drug may interact with other drugs or health problems.

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.
- You may need to take certain supplements like vitamin A, D, E, and K while taking this drug. Be sure to follow what your doctor has told you.
- This drug may raise the chance of a broken bone. Talk with the doctor.
- If your weight changes, talk with your doctor. The dose of this drug may need to be changed.

- 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 liver problems like dark urine, tiredness, decreased appetite, upset stomach or stomach pain, light-colored stools, throwing up, or yellow skin or eyes.
- Signs of an enlarged spleen like left upper stomach pain or shoulder pain.
- Signs of gallstones like sudden pain in the upper right belly area, right shoulder area, or between the shoulder blades; yellow skin or eyes; or fever with chills.
- Any unexplained bruising or bleeding.

- Feeling very tired or weak.
- Bone pain.
- If you are having diarrhea, call the doctor right away if you have signs of dehydration like dry skin, mouth, or eyes; thirst; fast heartbeat; dizziness; fast breathing; or confusion.

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:

- Stomach pain.
- Throwing up.
- Weight loss.
- Headache.
- Constipation.
- Diarrhea is common with this drug and can be severe. Call your doctor to find out what to do if you have diarrhea or stomach cramps. You will need to take care not to become dehydrated. Do not try to treat diarrhea without first checking with your doctor.

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 in the morning.
- Take with a meal.
- Swallow whole with a full glass of water.
- Do not chew or crush.
- If this drug cannot be swallowed whole, you may open the capsule and sprinkle the contents on a small amount (up to 2 tablespoons or 30 mL) of soft food like applesauce, oatmeal, banana or carrot puree, or chocolate or rice pudding. The soft food needs to be at or below room temperature. Gently mix. Swallow the mixture right away. Do not store for future use. Follow the dose with water.

- This drug may also be mixed with 5 mL (1 teaspoon) of liquid like water. If giving this drug to an infant, it may be mixed in breast milk or infant formula. Let the contents sit in the liquid for about 5 minutes. This drug will not dissolve. Swallow the mixture right away. Do not store for future use. Follow the dose with liquid.
- 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.
- Some drugs may have another patient information leaflet. Check with your pharmacist. If you have any questions about this drug, please talk with your doctor, nurse, 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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