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 the doctor BEFORE my child takes this drug?

- If your child is allergic to this drug; any part of this drug; or any other drugs, foods, or substances. Tell the doctor about the allergy and what signs your child had.
- If your child has liver problems or has had severe effects caused by liver problems.

This drug may interact with other drugs or health problems.

Tell the doctor and pharmacist about all of your child's drugs (prescription or OTC, natural products, vitamins) and health problems. You must check to make

sure that it is safe to give this drug with all of your child's other drugs and health problems. Do not start, stop, or change the dose of any drug your child takes without checking with the doctor.

What are some things I need to know or do while my child takes this drug?

- Tell all of your child's health care providers that your child is taking this drug. This includes your child's doctors, nurses, pharmacists, and dentists.
- Have your child's blood work and other lab tests checked as you have been told by the doctor.
- Your child may need to take certain supplements like vitamin A, D, E, and K while taking this drug. Be sure to follow what the doctor has told you.
- This drug may raise the chance of a broken bone. Talk with the doctor.
- If your child's weight changes, talk with the doctor. The dose of this drug may need to be changed.

If your child is pregnant or breast-feeding a baby:

- Talk with the doctor if your child is pregnant, becomes pregnant, or is breast-feeding a baby. You will need to talk about the benefits and risks to your child and the baby.

What are some side effects that I need to call my child's 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 child's doctor or get medical help right away if your child has 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 your child is having diarrhea, call the doctor right away if your child has 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 child's doctor or get medical help if any of these side effects or any other side effects bother your child or do not go away:

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

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

about side effects.

You may report side effects to your national health agency.

How is this drug best given?

Give this drug as ordered by your child's doctor. Read all information given to you. Follow all instructions closely.

All products:

- Give in the morning.
- Give with a meal.
- Do not give colesevelam, colestipol, or cholestyramine within 4 hours before or 4 hours after this drug.

Capsules:

- Have your child swallow whole with a full glass of water.
- Do not let your child chew or crush.
- If your child cannot swallow this drug 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. Have your child swallow the mixture right away. Do not store for future use. Have your child follow the dose with water.
- This drug may also be mixed with 5 mL (1 teaspoon) of liquid like water, breast milk, or infant formula. Let the contents sit in the liquid for about 5 minutes. This drug will not dissolve. Have your child swallow the mixture right away. Do not store for future use. Follow the dose with water, breast milk, infant formula, or other liquid.

Oral pellets:

- Do not swallow whole. Do not chew or crush.
- Open the shell and sprinkle the pellets in up to 30 mL (2 tablespoons) 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. Have your child swallow the mixture right away. Do not store for future use. Have your child follow the dose with water.
- If your child is not able to swallow soft food: The pellets may be mixed in liquid and given with an oral syringe. Do not use a bottle or sippy cup because the pellets will not fit through the opening.
- Open the shell and sprinkle the pellets into a small cup. Add 5 mL (1 teaspoon) liquid like water, breast milk, or infant formula. If the dose is more than one shell, repeat. Let the pellets sit in the liquid for about 5 minutes. The pellets will not dissolve.
- After 5 minutes, place the tip of an oral syringe into the liquid. Draw up the mixture then push it back into the cup. Do this 2 or 3 times to help mix. Give right away. Do not store for future use.
- Draw the mixture into the syringe. Place the tip of the syringe in your child's mouth and gently push the mixture into the area between the tongue and cheek. Do not squirt into the back of the throat. This could cause gagging or choking.
- Follow the dose with water, breast milk, infant formula, or other liquid.
- If any of the mixture is still in the cup, repeat until the whole dose is taken. Check your child's mouth to be sure the whole dose has been swallowed.

What do I do if my child misses a dose?

- Give a missed dose as soon as you think about it.
- If it is close to the time for your child's next dose, skip the missed dose and go back to your child's normal time.
- Do not give 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 child's symptoms or health problems do not get better or if they become worse, call your child's doctor.
- Do not share your child's drug with others and do not give anyone else's drug to your child.
- Some drugs may have another patient information leaflet. If you have any questions about this drug, please talk with your child's 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,

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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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