

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

PrBYLVAY™

Odevixibat capsules

Read this carefully before you start taking **BYLVAY** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **BYLVAY**.

What is BYLVAY used for?

BYLVAY is used to treat itch in progressive familial intrahepatic cholestasis (PFIC) in patients aged 6 months or older. PFIC is a liver disease caused by build-up of bile acids (cholestasis) that gets worse over time and is often accompanied with severe itching.

How does BYLVAY work?

BYLVAY contains the active substance odevixibat. Odevixibat is a medicine which increases the removal of substances called bile acids from the body. Bile acids are components of the digestive fluid called bile. It is produced by the liver and secreted into the intestines. Odevixibat blocks the mechanism that normally reabsorbs them from the intestines after they have done their job. This allows them to pass out of the body in the stool.

What are the ingredients in BYLVAY?

Medicinal ingredients: odevixibat sesquihydrate

Non-medicinal ingredients: Black iron oxide, hypromellose, microcrystalline cellulose, propylene glycol, red iron oxide (400 mcg and 1200 mcg capsules only), shellac, titanium dioxide, yellow iron oxide

BYLVAY comes in the following dosage forms:

Capsules, 200 mcg, 400 mcg, 600 mcg and 1200 mcg

Do not use BYLVAY if:

- You are allergic to any ingredients in this drug.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take BYLVAY. Talk about any health conditions or problems you may have, including if you:

- been diagnosed with a complete absence or lack of function of bile salt export pump protein
- severely reduced liver function
- reduced stomach or bowel motility (movement of food throughout the body), or reduced circulation of bile acids between liver, bile and small intestine due to medicines, and/or surgical procedures.

Other warnings you should know about:

Talk to your doctor if you develop diarrhoea while taking BYLVAY. If you have diarrhoea, drink enough liquid to prevent dehydration.

Your doctor may recommend more frequent monitoring if you have abnormal liver function test results.

Your doctor may recommend assessment of Vitamin A, D and E blood levels and the blood clotting value called INR prior to and during BYLVAY treatment.

Children

Bylvay is not recommended for babies under 6 months because it is not known if the medicine is safe and effective in this age group.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.

BYLVAY is not recommended during pregnancy and in women who can get pregnant but are not using contraception.

It is not known if BYLVAY can pass into breast milk and affect the baby. Your doctor will help you to decide whether to stop breast-feeding or avoid BYLVAY treatment.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may interact with BYLVAY:

- Treatment with BYLVAY may affect the absorption of fat-soluble vitamins such as Vitamin A, D and E, calcium, and fat-soluble medicines.

How to take BYLVAY:

- 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 dose of BYLVAY is based on your weight. Your doctor will work out the right number and strength of capsules for you to take.

Usual dose:

40 micrograms BYLVAY per kilogram body weight once daily

If the medicine is not working well enough after 3 months, your doctor may increase the dose to 120 micrograms BYLVAY per kilogram body weight (up to a maximum of 7200 micrograms once daily).

Take the capsules once daily in the morning with a meal.

All capsules can be either swallowed whole with a glass of water or opened and sprinkled on soft food or in a liquid.

Instructions to open capsules and sprinkle the contents on soft food:

Step 1: Place a small amount of soft food into a bowl (2 tablespoons/30 mL of yoghurt, apple sauce, banana or carrot puree, chocolate pudding, rice pudding or oatmeal porridge). Food should be at or below room temperature.



Step 2: Hold the capsule horizontally at both ends, twist in opposite directions.

Step 3: Pull apart to empty the contents into the bowl of soft food.

Step 4: Gently tap the capsule to ensure that all pellets come out.

Step 5: Repeat Steps 2, 3, and 4 if the dose requires more than one capsule.

Step 6: Gently mix the contents of the capsule into the soft food. Note that the pellets will not dissolve.

Step 7: Take the entire dose mixed into the soft food right away. Do not store the mixture for future use.

Step 8: Drink water or give an age-appropriate liquid, such as breast milk or infant formula, after the dose is taken to make sure any remaining soft food and pellet mixture is swallowed.

Step 9: Throw away all empty capsule shells in the trash.

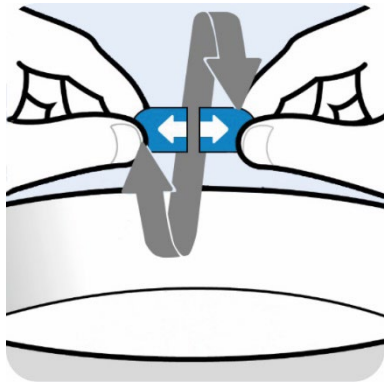
Instructions to open capsules and sprinkle the contents in liquids:

If you are sprinkling the contents of the capsules in a liquid, you will need to use an oral syringe that holds 5mL or more.

Do not administer using a bottle or “sippy cup” because the liquid and pellet mixture will not pass through the opening. The pellets do not dissolve in liquids.

Step 1: Give BYLVAY with the first morning meal.

Step 2: Hold the capsule horizontally at both ends, twist in opposite directions.



Step 3. Pull apart and empty the contents into a small mixing cup.



Step 4: Gently tap the capsule shell to ensure that all pellets have been emptied into the mixing cup.

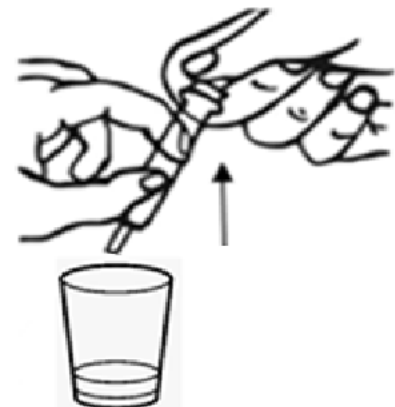
Step 5. If the dose requires more than 1 capsule, repeat Steps 2, 3, and 4.

Step 6. Add 1 teaspoon (5 mL) of an age-appropriate liquid (for example, breast milk, infant formula, or water).

Step 7. Let the pellets sit in the liquid for about 5 minutes to allow complete wetting. REMINDER: The pellets will not dissolve in the liquid.

Step 8. After 5 minutes, place the tip of the oral syringe completely into the mixing cup. Pull the plunger of the syringe up slowly to withdraw the liquid and pellet mixture into the syringe. Gently push the plunger down again to expel the liquid and pellet mixture back into the mixing cup. Do this 2 to 3 times to ensure complete mixing of the pellets into the liquid.

Step 9. Withdraw the entire contents of the mixing cup into the syringe by pulling the plunger on the end of the syringe.



Step 10. Place the tip of the syringe between the tongue and the side of the mouth, and then gently push the plunger down to squirt the liquid and pellet mixture between the tongue and the side of the mouth. Do not squirt the liquid and pellet mixture in the back of the throat because this could cause gagging or choking.



Step 11. Repeat Steps 9 and 10 until the entire dose (all of the liquid and pellet mixture in the cup) has been given. Do not store the mixture for future use.

Step 12. Drink water or give an age-appropriate liquid, such as breast milk or infant formula, to make sure any liquid and pellet mixture remaining in the mouth is swallowed.

Step 13. Dispose of (throw away) all empty capsule shells in the trash.

Overdose:

If you or the person you are caring for have taken too much BYLVAY, you may have side effects such as vomiting and diarrhea.

If you think you, or a person you are caring for, have taken too much BYLVAY, contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

Missed Dose:

Do not take a double dose to make up for a forgotten dose. Take the next dose at the usual time.

What are possible side effects from using BYLVAY?

These are not all the possible side effects you may have when taking BYLVAY. If you or your child experience any side effects not listed here, tell your healthcare professional.

Side effects may include:

- vomiting
- diarrhea
- abdominal (belly) pain

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

- Store BYLVAY at room temperature (15°C to 30°C). Protect from exposure to light.
- Keep out of the reach and sight of children.

If you want more information about BYLVAY:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website: <https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>; the manufacturer's website www.medisonpharma.com, or by calling 1-800-696-1341

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