

BYLVAY Administration with Liquids

Quick Reference Guide



This resource contains basic information on how to give BYLVAY and does not replace the [Instructions for Use](#). If you have additional questions, contact your healthcare provider or pharmacy before administering BYLVAY.



What is BYLVAY (odevixibat)?

BYLVAY is a prescription medicine for the treatment of itching in:

- Patients 12 months of age and older with Alagille syndrome (ALGS)
- Patients 3 months of age and older with progressive familial intrahepatic cholestasis (PFIC)

Limitation of Use:

BYLVAY is not recommended for some PFIC type 2 patients who have specific *ABCB11* gene changes. Talk with your healthcare provider if you have questions.

Important information you should know before giving or taking BYLVAY



Give BYLVAY **along with the morning meal.**



BYLVAY Oral Pellets are to be opened and sprinkled.

Do not let your child swallow the shell containing the Oral Pellets.



Mix BYLVAY with an age-appropriate liquid and give through an oral syringe.

Do not give using a bottle or “sippy cup” because the Oral Pellets will not pass through the opening.

The Oral Pellets will not dissolve in liquid.



If your child is taking bile acid binding resins (for example, cholestyramine, colestipol), give them BYLVAY at least 4 hours before or 4 hours after they take the bile acid binding resin.



If you or your child have been prescribed oral capsules, and are unable to swallow the capsule whole, BYLVAY capsules may also be opened and mixed with soft food or liquids by following the directions for oral pellets.

Please see Important Safety Information on page 4 of this guide and full [Prescribing Information](#), including [Instructions for Use](#), at [BYLVAY.com](#)

Preparing to give BYLVAY Oral Pellets with liquids:

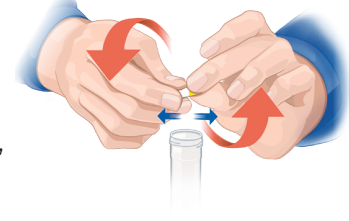
Step 1

Give BYLVAY with the first morning meal.



Step 2

Hold the shell horizontally on both ends, twist in opposite directions, and pull apart.



Step 3

Empty the Oral Pellets into a mixing cup.

Gently tap the shell containing Oral Pellets to make sure that all pellets come out.



Step 4

If the dose requires more than 1 capsule shell, repeat Steps 2 and 3.



Step 5

Into the mixing cup, add 1 teaspoon (5 mL) of an age-appropriate liquid, such as breast milk, formula, juice, or water.



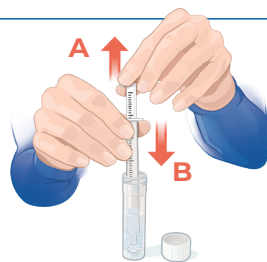
Step 6

Let the pellets sit in the liquid for **5 minutes**.



Step 7

Next, completely submerge the tip of the oral syringe into the liquid in the mixing cup.



A Pull the plunger of the syringe up slowly to withdraw the liquid and pellet mixture.

B Gently push the plunger down again to expel the mixture back into the mixing cup.

Repeat 2 to 3 times to ensure complete mixing of the pellets into the liquid.
The Oral Pellets will not dissolve.



Step 8

Withdraw the entire contents into the syringe by pulling the plunger on the end of the syringe.

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Giving BYLVAY Oral Pellets with liquids (using an oral dosing syringe):

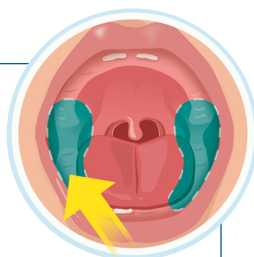
Step 9

Place the tip of the syringe into the front of the child's mouth between the tongue and the side of the mouth.



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 10

Repeat Steps 8 and 9 until the entire dose has been given. Check to make sure all of the liquid and pellet mixture has been swallowed.

Step 11

Give water or an age-appropriate liquid after the dose is taken.

Step 12

Dispose of (throw away) the empty Oral Pellet shells in the trash.

Storage and extra considerations

How should I store BYLVAY Capsules or Oral Pellets?

Store BYLVAY at room temperature between 68°F to 77°F (20°C to 25°C).

Disposing of BYLVAY Capsules or Oral Pellets shells.

Dispose of the empty BYLVAY Capsule or Oral Pellets shells in the household trash.

IPSENCARES[®]

Coverage, Access, Reimbursement & Education Support

IPSEN CARES patient support program can help you get access to your BYLVAY[®] (odevixibat) prescription with the information and support you need.

To learn more about IPSEN CARES:

IPSENCARES.com
(866) 435-5677
Monday-Friday,
8:00 AM–8:00 PM ET
support@ipsencares.com

Scan to
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IMPORTANT SAFETY INFORMATION for BYLVAY (odevixibat):

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- Patients 3 months of age and older with progressive familial intrahepatic cholestasis (PFIC)

Limitation of Use:

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What are the possible side effects of BYLVAY?

BYLVAY can cause serious effects, including:

- You should not use BYLVAY if you have had or have an advanced stage of liver disease. Talk with your healthcare provider if you have any liver conditions.
- Abnormal liver tests have been observed with use of BYLVAY. Liver tests should be obtained before starting and periodically during therapy to monitor for liver injury. Immediately report to your healthcare provider any signs or symptoms of liver injury, such as nausea, vomiting, skin or the whites of eyes turn yellow, dark or brown urine, pain on the right side of the abdomen, or loss of appetite.
- Notify your healthcare provider if you experience new onset or worsening of diarrhea.
- BYLVAY may decrease the absorption of certain vitamins, which include vitamins A, D, E, and K (FSV or fat-soluble vitamins). Your blood levels of these vitamins should be measured before starting and periodically during treatment to assess for FSV deficiency. You may bleed more easily, bleed longer, or experience a bone fracture. Call your healthcare provider if you have any signs or symptoms of bleeding.

The most common side effects of BYLVAY include:

- The most common side effects of BYLVAY treatment in patients with ALGS are diarrhea, abdominal pain, abnormal bleeding, such as bruising, and decreased weight.
- The most common side effects of BYLVAY in patients with PFIC are diarrhea, liver test abnormalities, vomiting, abdominal pain, and FSV deficiency.
- Do not swallow the 200 mcg or 600 mcg capsule(s) containing Oral Pellets whole. These are intended to be opened and the contents mixed into soft food.
- For patients taking bile acid binding resins, take BYLVAY at least 4 hours before or 4 hours after taking a bile acid binding resin.
- There is a pregnancy safety study that collects outcome data in women taking BYLVAY during pregnancy. Pregnant women exposed to BYLVAY should report if they have used BYLVAY during pregnancy by calling 1-855-463-5127 and contact your doctor immediately.

You are encouraged to report side effects to FDA at 1-800-FDA-1088 or at www.fda.gov/medwatch. You may also report side effects to Ipsen Biopharmaceuticals, Inc. at 1-855-463-5127.

Please see full [Prescribing Information](#), including [Instructions for Use](#), at BYLVAY.com

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BYL-US-002680 v2.0 02/2026