

Building a routine with Bylvay[®] (odevixibat)

Incorporating a new medication into your daily routine doesn't have to be challenging. With proper guidance and direction, it can become second nature. See the final page for tips to help make Bylvay a part of your routine.

Bylvay can be taken 3 ways



Mixed with
food



Mixed with
liquids



Swallowed
whole

Use this booklet for clear and concise steps on preparing and administering Bylvay for yourself or your child.

Instructions for use: Bylvay [bil-vay]

Capsules, for oral use | Oral Pellets

This Instructions for Use contains information on how to give Bylvay Capsules and Oral Pellets. This information does not take the place of talking to your healthcare provider about your child's medical condition or their treatment.

Important information you need to know before giving or taking Bylvay

- Give Bylvay **along with the morning meal**
- Mix Bylvay in a small amount of soft food (up to 2 tablespoons [30 mL]), such as apple sauce, oatmeal, banana or carrot puree, chocolate or rice pudding, in a bowl. You may also mix Bylvay with an age-appropriate liquid and give through an oral syringe
- 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

Preparing to give Bylvay

You will be provided with the number of BYLVAY Capsules or Oral Pellets prescribed by your child's healthcare provider in a child-resistant closure.

Uses

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

Please see [Important Safety Information](#) throughout, and the full [Prescribing Information](#).



200 | 400 | 600 | 1200 mcg capsules



Giving Bylvay Oral Pellets with soft food

- The shell containing Oral Pellets is to be opened and sprinkled. **Do not** let your child swallow the shell containing the Oral Pellets. Dispose of (throw away) the emptied shell
- Mix the contents of the Oral Pellets with soft food as shown in **Steps 1 through 9** below



Steps

1

Give Bylvay with the first morning meal. Place a small amount of soft food (up to 2 tablespoons [30 mL], such as apple sauce, oatmeal, banana or carrot puree, chocolate or rice pudding) in a bowl. Keep the soft food at, or cooler than, room temperature. Note: This small amount of soft food should be less than what your child would normally eat.

2

Hold the shell containing Oral Pellets horizontally on both ends, twist in opposite directions, and pull apart (see **Figure A**).

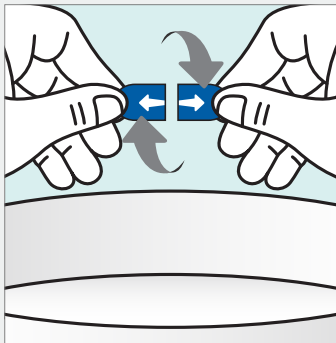


Figure A

A200
Oral Pellets
200 mcg

A600
Oral Pellets
600 mcg

3

Empty the Oral Pellets into the bowl of soft food (see **Figure B**).

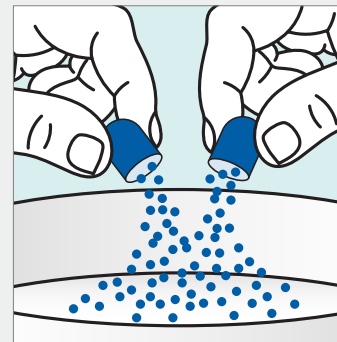


Figure B

IMPORTANT SAFETY INFORMATION

- 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.

Please see [Important Safety Information](#) throughout, and the full [Prescribing Information](#).



Giving Bylvay Oral Pellets with soft food (cont'd)

Steps

4

Gently tap the shell containing Oral Pellets to make sure that all pellets come out (see **Figure C**).

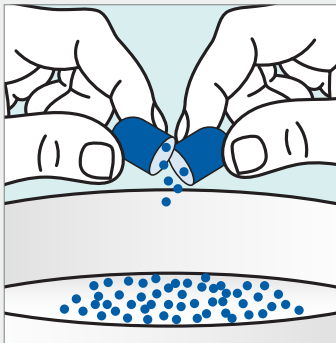


Figure C

5

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

6

Gently mix the Oral Pellets with a spoon into the soft food (see **Figure D**). Note that the Oral Pellets will not dissolve.

Figure D



7

Give the entire dose right away after mixing. **Do not** store the Bylvay mixture for later use.

8

Give water or an age-appropriate liquid, such as breast milk or infant formula, after the dose is taken.

9

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

Click this code to find a video on how Bylvay Oral Pellets are opened and sprinkled.



IMPORTANT SAFETY INFORMATION (CONT'D)

- 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.

Please see [Important Safety Information](#) throughout, and the full [Prescribing Information](#).



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

- The shell containing the Oral Pellets is to be opened
- Mix the Oral Pellets with liquid as shown in **Steps 1 through 14** below
- Dispose of (throw away) the emptied shells. **Do not** let your child swallow the unopened shells containing the Oral Pellets



Steps

1

Give Bylvay with the first morning meal.

2

Hold the shell containing the Oral Pellets horizontally on both ends, twist in opposite directions and pull apart (see **Figure A**).

3

Empty the Oral Pellets into a small mixing cup. Gently tap the Oral Pellet shell to ensure that all contents have been emptied into the mixing cup (see **Figure E**).

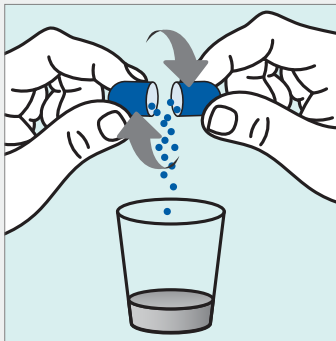


Figure E

A200

Oral Pellets
200 mcg

A600

Oral Pellets
600 mcg

4

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

5

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

6

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

IMPORTANT SAFETY INFORMATION (CONT'D)

- Notify your healthcare provider if you experience new onset or worsening of diarrhea.

Please see [Important Safety Information](#) throughout, and the full [Prescribing Information](#).



Giving Bylvay Oral Pellets with liquids (using an oral dosing syringe) (cont'd)

Steps

7

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.

8

Withdraw the entire contents into the syringe by pulling the plunger on the end of the syringe (see **Figure F**).

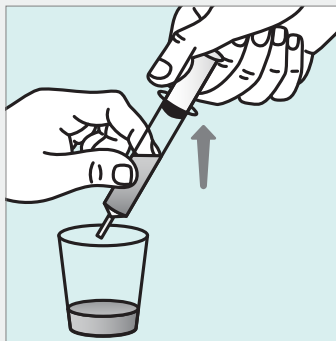


Figure F

9

Place the tip of the syringe into the front of the child's mouth 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 (see **Figure G**).

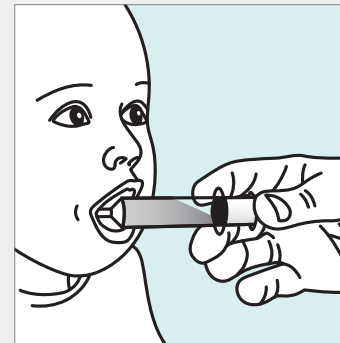


Figure G

IMPORTANT SAFETY INFORMATION (CONT'D)

- 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 or may bleed longer. Call your healthcare provider if you have any signs or symptoms of bleeding.
- The most common side effects of BYLVAY treatment in patients with ALGS are diarrhea, abdominal pain, abnormal bleeding, such as bruising, and decreased weight.

Please see [Important Safety Information](#) throughout, and the full [Prescribing Information](#).



Giving Bylvay Oral Pellets with liquids (using an oral dosing syringe) (cont'd)

Steps

10

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.

11

Give water or an age-appropriate liquid, such as breast milk or infant formula after the dose is taken.

12

Repeat **Steps 8 and 9** until the entire dose has been given.

13

Check to make sure all of the liquid and pellet mixture has been swallowed.

14

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

Click this code to see a video that will take you through the steps of mixing Bylvay with liquid.



IMPORTANT SAFETY INFORMATION (CONT'D)

- 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.

Please see [Important Safety Information](#) throughout, and the full [Prescribing Information](#).



Taking Bylvay Capsules

- Take Bylvay Capsules **along with your morning meal**. Swallow Bylvay Capsules whole with a glass of water. **Do not** chew or crush the Capsules
- For children unable to swallow Bylvay Capsules whole, follow instructions under **Preparing to give Bylvay** above



Capsules
400 mcg



Capsules
1200 mcg

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 (throwing away) Bylvay Capsules or Oral Pellets shells

Dispose of (throw away) the empty Bylvay Capsule or Oral Pellets shells in the household trash.

What are the ingredients in Bylvay?

Active ingredient: odevixibat.

Inactive ingredients: hypromellose and microcrystalline cellulose.

IMPORTANT SAFETY INFORMATION (CONT'D)

- 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.

Please see [Important Safety Information](#) throughout, and the full [Prescribing Information](#).

Tips for building a daily routine



Set a daily reminder on your phone



Put a sticky note on the kitchen counter/cabinet



Use a days-of-the-week pillbox

Questions about taking or administering Bylvay?

Talk to your doctor if you have questions about taking or administering Bylvay. You can also contact IPSEN CARES for information about Bylvay.



1-866-435-5677



[IPSECARES.com](https://www.ipsecares.com)

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- Notify your healthcare provider if you experience new onset or worsening of diarrhea.
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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 at 1-855-463-5127.

Please see full Prescribing Information for BYLVAY.

Please see the full [Prescribing Information](#).

 **Bylvay**[®]
(odevixibat)