

**Instructions For Use  
BYLVAY [bil-vay]  
(odevixibat)  
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.

**Giving BYLVAY Oral Pellets with soft food:**

- The shell containing Oral Pellets are 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.

**Step 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.

**Step 2.** Hold the shell containing Oral Pellets horizontally on both ends, twist in opposite directions and pull apart (see **Figure A**).

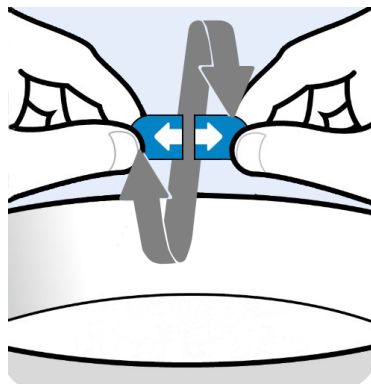


Figure A

**Step 3.** Empty the Oral Pellets into the bowl of soft food (see **Figure B**).

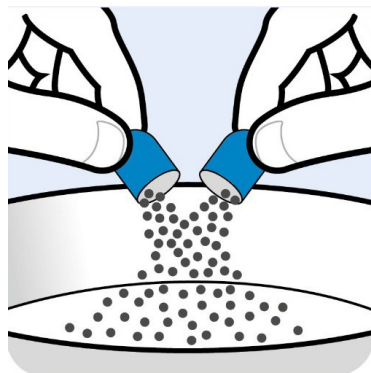


Figure B

**Step 4.** Gently tap the shell containing Oral Pellets to make sure that all pellets come out (see **Figure C**).

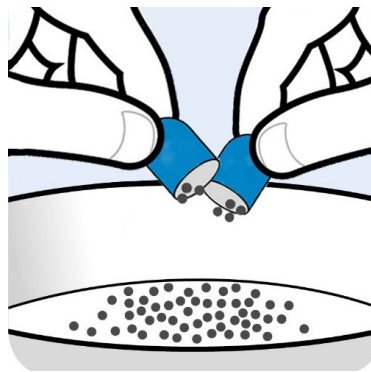


Figure C

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

**Step 6.** Gently mix the Oral Pellets with a spoon into the soft food. Note that the Oral Pellets will not dissolve (see **Figure D**).



**Figure D**

- Step 7.** Give the entire dose right away after mixing. **Do not** store the BYLVAY mixture for later use.
- Step 8.** Give water or an age-appropriate liquid, such as breast milk or infant formula, after the dose is taken.
- Step 9.** Dispose of (throw away) the empty Oral Pellet shells in the trash.

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

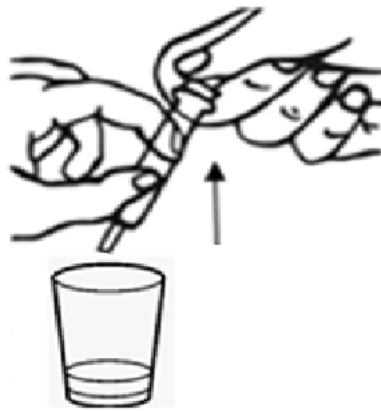
- The shell containing the Oral Pellets are to be opened.
- Mix the Oral Pellets with liquid as shown in **Steps 1 through 14** below.
- Dispose of (throw away) the emptied shells. **Do not** let your child swallow the unopened shells containing the Oral Pellets.

- Step 1.** Give BYLVAY with the first morning meal.
- Step 2.** Hold the shell containing the Oral Pellets horizontally on both ends, twist in opposite directions and pull apart (see **Figure A**).
- Step 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**

- Step 4.** If the dose requires more than 1 capsule shell, repeat **Step 2** and **Step 3**.
- Step 5.** Add 1 teaspoon (5 mL) of an age-appropriate liquid (for example, breast milk, infant formula, or water).
- Step 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.
- Step 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.
- Step 8.** Withdraw the entire contents into the syringe by pulling the plunger on the end of the syringe (see **Figure F**).



**Figure F**

**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, 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**

- Step 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.
- Step 11.** Give water or an age-appropriate liquid such as breast milk or infant formula after the dose is taken.
- Step 12.** Repeat Steps 8 and 9 until the entire dose has been given.
- Step 13.** Check to make sure all of the liquid and pellet mixture has been swallowed.
- Step 14.** Dispose of (throw away) the empty Oral Pellet shells in the trash.

### **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.

### **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 (throwing away) of 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.

Manufactured for:

Ipsen Biopharmaceuticals, Inc.  
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Cambridge, MA 02142

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This Instructions for Use has been approved by the U.S. Food and Drug Administration.

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