

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. Do not mix BYLVAY in liquids like breast milk, formula, or water.**
- 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.
- **Do not** give BYLVAY to children who only take liquids (for example, breast milk, formula, or water).
- 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:

- The Oral Pellets are to be opened and sprinkled. **Do not** let your child swallow the capsule shell containing the Oral Pellets.
- Mix the contents of the Oral Pellets with soft food as shown in **Steps 1 through 8** below.

Step 1. Place a small amount of soft food (up to 2 tablespoons, 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**).

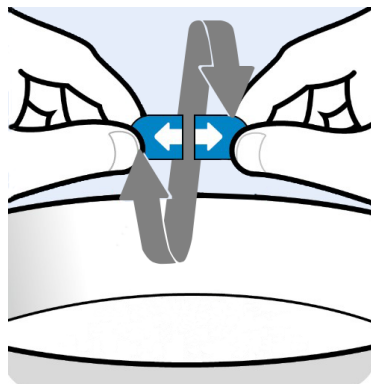


Figure A

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

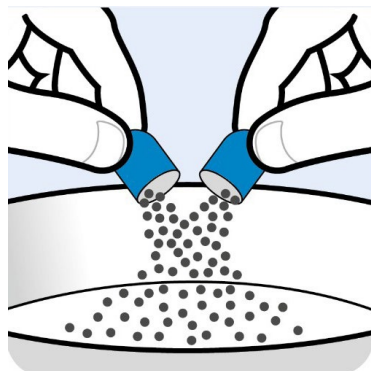


Figure B

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

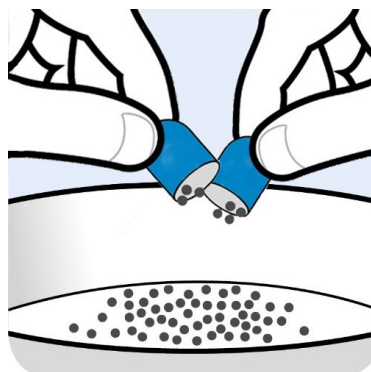


Figure C

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

Step 5. Gently mix the Oral Pellets with a spoon into the soft food. Please note that the Oral Pellets will not dissolve (see **Figure D**).



Figure D

- Step 6.** Give the entire dose right away after mixing. **Do not** store the BYLVAY mixture for later use.
- Step 7.** Give water after the dose is taken.
- Step 8.** Dispose of (throw away) the empty Oral Pellets shell(s) 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 **Steps 1 through 8** 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 (throw away) the empty BYLVAY Capsule or Oral Pellets shell(s) in the household trash.

What are the ingredients in BYLVAY?

Active ingredient: odevixibat.

Inactive ingredients: hypromellose and microcrystalline cellulose.

Manufactured for:

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