Bylvay™
(odevixibat)
200 | 400 | 600 | 1200 mcg capsules

Now Approved

For Patients 3 Months and Older

Dosage and Administration

Bylvay is an ileal bile acid transporter (IBAT) inhibitor indicated for the treatment of pruritus in patients aged 3 months of age and older, with progressive familial intrahepatic cholestasis (PFIC).

Limitation of Use: PFIC type 2 patients with truncating ABCB11 mutations (Bile Salt Export Pump [BSEP]-3)

Please see Important Safety Information.

Click here for Full Prescribing Information.

Administration

Preparation and Administration Instructions

- **For patients taking bile acid binding resins, take Bylvay at least 4 hours before or 4 hours after taking a bile acid binding resin.**
- **Do not crush or chew capsules.**

Oral Pellets:

- Mix the contents of the shell containing oral pellet(s) into soft food. Do not mix Bylvay in liquids.
- Do not swallow the shell containing oral pellets whole.
- Patients who are exclusively on liquid food should not use Bylvay.

Administration Instructions:

1. Take Bylvay in the morning with a meal.
2. Place a small amount of soft food (up to 30 mL [2 tablespoons] of apple sauce, oatmeal, banana or carrot puree, chocolate or rice pudding) in a bowl. Keep food at or below room temperature.
3. Open the shell containing oral pellet(s) and empty the contents into the bowl of soft food. Gently tap the oral pellet shell to ensure that all contents have been dispersed.
4. If the dose requires more than one shell of oral pellets, repeat step 2 and step 3.
5. Gently mix until well dispersed and administer the entire dose immediately.
6. Follow the dose with water.
7. Do not store mixture for future use.

Capsules:

Administration Instructions:

1. Take in the morning with a meal.
2. Swallow the capsule whole with a glass of water.
3. Alternatively, for patients unable to swallow the capsules whole, Bylvay capsules may be opened, and sprinkled and mixed with a small amount of soft food. Follow directions above for oral pellets to prepare and administer such a mixture.

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200 | 400 | 600 | 1200 mcg capsules

Recommended Dosing for Bylvay (odevixibat)

Dosage Forms and Strengths

Bylvay is currently available in 200 mcg Oral Pellets, and 400 mcg and 1200 mcg Capsules.

Recommended Dosage of Bylvay for
40 mcg/kg/day

Body Weight (kg)	Total Daily Dose (mcg)	Number of Oral Pellets or Capsules
7.4 and below	200	1 (200 mcg Oral Pellet)
7.5 to 12.4	400	2 (200 mcg Oral Pellets)
12.5 to 17.4	600	3 (200 mcg Oral Pellets)
17.5 to 19.4	800	4 (200 mcg Oral Pellets)
19.5 to 25.4	800	2 (400 mcg Capsules)
25.5 to 35.4	1200	1 (1200 mcg Capsule)
35.5 to 45.4	1600	4 (400 mcg Capsules)
45.5 to 55.4	2000	5 (400 mcg Capsules)
55.5 and above	2400	2 (1200 mcg Capsules)

If there is no improvement in pruritus after 3 months, the dosage may be increased in 40 mcg/kg increments up to 120 mcg/kg once daily not to exceed a total daily dose of 6 mg.

How Supplied/Storage and Handling

Bylvay capsules are supplied in bottles of 30 with child-resistant closure.
Store at 20°C to 25°C (68°F to 77°F).

Recommended Dosing for Bylvay (odevixibat)

Recommended Dosage of Bylvay for 80 mcg/kg/day

Body Weight (kg)	Total Daily Dose (mcg)	Number of Oral Pellets or Capsules
7.4 and below	400	2 (200 mcg Oral Pellets)
7.5 to 12.4	800	4 (200 mcg Oral Pellets)
12.5 to 17.4	1200	1 (1200 mcg Capsule)*
17.5 to 19.4	1600	8 (200 mcg Oral Pellets)
19.5 to 25.4	1600	4 (400 mcg Capsules)
25.5 to 35.4	2400	2 (1200 mcg Capsules)
35.5 to 45.4	3200	8 (400 mcg Capsules)
45.5 to 55.4	4000	10 (400 mcg Capsules)
55.5 and above	4800	4 (1200 mcg Capsules)

*Open 1200 mcg Capsules and sprinkle on food for child unable to swallow capsule whole.

Recommended Dosage of Bylvay for 120 mcg/kg/day

Body Weight (kg)	Total Daily Dose (mcg)	Number of Oral Pellets or Capsules
7.4 and below	600	3 (200 mcg Oral Pellets)
7.5 to 12.4	1200	1 (1200 mcg Capsule)*
12.5 to 17.4	1800	9 (200 mcg Oral Pellets)
17.5 to 19.4	2400	2 (1200 mcg Capsules)*
19.5 to 25.4	2400	2 (1200 mcg Capsules)
25.5 to 35.4	3600	3 (1200 mcg Capsules)
35.5 to 45.4	4800	4 (1200 mcg Capsules)
45.5 and above	6000	5 (1200 mcg Capsules)

*Open 1200 mcg Capsules and sprinkle on food for child unable to swallow capsule whole.

Please see Important Safety Information.

Click here for Full Prescribing Information.

Important Safety Information

Warnings and Precautions:

Liver Test Abnormalities

Patients enrolled in a clinical trial had abnormal liver tests at baseline. In a clinical trial, treatment-emergent elevations of liver tests or worsening of liver tests relative to baseline values were observed during the clinical trial. Most abnormalities included elevation in AST, ALT, or total and direct bilirubin. Treatment interruption days ranged from 3 days to 124 days; none of the patients in the pivotal clinical trial permanently discontinued treatment due to liver test abnormalities.

Obtain baseline liver tests and monitor during treatment. Dose reduction or treatment interruption may be required if abnormalities occur. For persistent or recurrent liver test abnormalities, consider treatment discontinuation.

Bylvay was not evaluated in PFIC patients with cirrhosis. Closely monitor for liver test abnormalities; permanently discontinue Bylvay if a patient progresses to portal hypertension or experiences a hepatic decompensation event.

Diarrhea

In a clinical trial, diarrhea was reported in 2 (10%) placebo-treated patients, 9 (39%) Bylvay-treated 40 mcg/kg/day patient and 4 (21%) Bylvay-treated 120 mcg/kg/day patients. Treatment interruption due to diarrhea, occurred in 2 patients with 3 events during treatment with Bylvay 120 mcg/kg/day. Treatment interruption due to diarrhea ranged between 3 to 7 days. One patient treated with Bylvay 120 mcg/kg/day withdrew from the pivotal clinical trial due to persistent diarrhea.

If diarrhea occurs, monitor for dehydration and treat promptly. Interrupt Bylvay dosing if a patient experiences persistent diarrhea. Restart Bylvay at 40 mcg/kg/day when diarrhea resolves, and increase the dose as tolerated if appropriate. If diarrhea persists and no alternate etiology is identified, stop Bylvay treatment.

Fat-Soluble Vitamin (FSV) Deficiency

Fat-soluble vitamins (FSV) include vitamin A, D, E, and K (measured using INR levels). PFIC patients can have FSV deficiency at baseline. Bylvay may affect absorption of fat-soluble vitamins. In a clinical trial, new onset or worsening of existing FSV deficiency was reported in 1 (5%) placebo-treated patient, and 3 (16%) Bylvay-treated 120 mcg/kg/day patients; none of the Bylvay-treated 40 mcg/kg/day patients had new onset or worsening of existing FSV deficiency.

Obtain serum FSV levels at baseline and monitor during treatment, along with any clinical manifestations. If FSV deficiency is diagnosed, supplement with FSV. Discontinue Bylvay if FSV deficiency persists or worsens despite adequate FSV supplementation.

Adverse Reactions

The most common adverse reactions for Bylvay are diarrhea, liver test abnormalities, vomiting, abdominal pain, and fat-soluble vitamin deficiency.

Drug Interactions

For patients taking bile acid binding resins, take Bylvay at least 4 hours before or 4 hours after taking a bile acid binding resin

Use in Specific Populations

There are no human data on Bylvay use in pregnant persons to establish a drug-associated risk of major birth defects, miscarriage, or adverse developmental outcomes. Based on findings from animal reproduction studies, Bylvay may cause cardiac malformations when a fetus is exposed during pregnancy.

Dedicated Support for Your Patients Taking Bylvay

Bylvay is backed by Albireo Assist, an in-house comprehensive support program specifically for patients prescribed Bylvay. Dedicated Albireo Assist Care Coordinators can provide:

Financial & Insurance Assistance

Care Logistics

Dedicated, Live Support

Educational Materials and Programs

For more information, or to speak with an Albireo Assist Care Coordinator, please call 855-ALBIREO (855-252-4736).

Visit Bylvay.com for more information

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