Bylvay offers flexible dosing for children and adults[1]

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

Once-daily dose taken with a morning meal[1]

No need to adjust meals before or after dosing—patients take Bylvay during their regular eating schedule

Bylvay Can Be Taken 3 Ways With 2 Oral Formulation Options[1]

Oral Pellets

For patients weighing <19.5 kg

Oral Pellets 200 mcg | Oral Pellets 600 mcg

Not actual size

Should not be swallowed whole

Shells can be opened and mixed with food

Shells can be opened and mixed with liquids*

Capsules

For patients weighing ≥19.5 kg

Capsules 400 mcg | Capsules 1200 mcg

Not actual size

Swallowed whole

Capsules can be opened and mixed with food

Capsules can be opened and mixed with liquids*

After mixing Bylvay with food or liquids, discard the empty shells.

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

Recommended Starting Dose[1]

Patients with pruritus in progressive familial intrahepatic cholestasis (PFIC)

40

mcg/kg/day

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 daily dosage of 6 mg/day.

Patients with cholestatic pruritus in Alagille syndrome

120

mcg/kg/day

Dose reduction to 40 mcg/kg/day may be considered if tolerability issues occur in the absence of other causes. Once tolerability issues stabilize, increase to 120 mcg/kg/day.

For a helpful dose-per-weight guide and complete instructions on dosage and administration, see the full **Prescribing Information**.

Indications and Usage

Bylvay is an ileal bile acid transporter (IBAT) inhibitor indicated for the treatment of cholestatic pruritus 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 may not be effective in a subgroup of PFIC type 2 patients with specific ABCB11 variants resulting in non-functional or complete absence of the bile salt export pump protein

IMPORTANT SAFETY INFORMATION

Warnings and Precautions:

Liver Test Abnormalities

Patients enrolled in PFIC and ALGS clinical trials had abnormal liver tests at baseline. In clinical trials, treatment-emergent elevations of liver tests or worsening of liver tests relative to baseline values were observed during the clinical trials.

In a clinical trial with PFIC patients, treatment-emergent elevations of liver tests or worsening of liver tests relative to baseline values were observed during the clinical trial. Most abnormalities included elevations in AST, ALT, or total and direct bilirubin. Treatment interruption days ranged from 3 days to 124 days; no PFIC patients permanently discontinued treatment due to liver test abnormalities.

Please see additional Important Safety Information on the back, and accompanying full Prescribing Information, also at https://bylvay.com.

Give your patients flexible administration options with Bylvay[1]

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

Bylvay is an IBATi that

- Offers a flexible formulation to accommodate pediatric and adult patients*
- Has no interactions with food
- Does not require fasting or delaying of meals

IBATi=ileal bile acid transporter inhibitor.
*For patients 12 months of age and older with Alagille syndrome or 3 months and older with PFIC.

IMPORTANT SAFETY INFORMATION (CONT'D)

Warnings and Precautions (cont'd):

Liver Test Abnormalities (cont'd)

In a clinical trial with ALGS patients, treatment-emergent elevations or worsening in liver tests relative to baseline values were observed during the trial. Most abnormalities included elevations in ALT or AST. One ALGS patient interrupted treatment for 40 days; no ALGS patients 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 or ALGS 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 PFIC clinical trial, diarrhea was reported in 2 (10%) placebo-treated patients, 9 (39%) Bylvay-treated 40 mcg/kg/day patients, 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.

In an ALGS clinical trial, diarrhea in ALGS patients was reported in 1 (6%) placebo-treated patient and in 10 (29%) Bylvay-treated patients. No patients interrupted or permanently discontinued Bylvay due to 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. In an ALGS clinical trial, new or worsening of existing FSV deficiency was reported in 3 (17.6%) placebo-treated patients and 3 (8.6%) Bylvay-treated patients.

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 in patients with PFIC are diarrhea, liver test abnormalities, vomiting, abdominal pain, and fat-soluble vitamin deficiency.

The most common adverse reactions for Bylvay patients with ALGS are diarrhea, abdominal pain, hematoma, and decreased weight.

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.

Please see additional Important Safety Information on the front, and accompanying full Prescribing Information, also at https://bylvay.com.

Reference: 1. Bylvay Prescribing Information. Cambridge, MA: Ipsen Biopharmaceuticals, Inc.; 2024.

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