For pruritus in your adult patients with progressive familial intrahepatic cholestasis (PFIC)

# BYLVAY® offers once-daily dosing and flexible administration[1]

**1** **daily dose** taken with a morning meal[1]

**2** **oral formulation options:** oral pellets, capsules[1]

**3** **ways to take:** swallow capsules whole; mix contents* with soft food or liquid[1]

*Pellets or capsules.

The **ONLY IBAT inhibitor** that:

- ✔ **OFFERS** once-daily dosing[2]
- ✔ **DOES NOT** require fasting or delaying of meals[2]
- ✔ **DOES NOT** require dose titration for standard treatment initiation[2]

## Capsules For patients weighing ≥19.5 kg[1]

Swallow whole | Open and mix with soft food | Open and mix with liquids†

Do not crush or chew capsules

## Oral Pellets For patients weighing <19.5 kg[1]

Do not swallow whole | Open and mix with soft food | Open and mix with liquids†

**After mixing BYLVAY with food or liquids, discard the empty shells.[1]**

†Add 1 teaspoon (5 mL of liquid) of an age-appropriate liquid.[1]

## Dosing for pruritus in PFIC[1]

- **Recommended starting dose** **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
- Dose should not exceed 6 mg/day

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

IBAT=ileal bile acid transporter.

## INDICATION

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

**Limitation of Use:**

BYLVAY is not recommended 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

**Contraindications**

IBAT inhibitors, including BYLVAY, are contraindicated in patients with prior or active hepatic decompensation events (e.g., variceal hemorrhage, ascites, hepatic encephalopathy).

**Please see additional Important Safety Information throughout and the full Prescribing Information.**

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

For pruritus in your adult patients with PFIC

# Take on the day with once-daily BYLVAY

## IMPORTANT SAFETY INFORMATION (CONT'D)
## WARNINGS AND PRECAUTIONS

### Hepatotoxicity

BYLVAY treatment is associated with a potential for drug-induced liver injury (DILI). In the PFIC trials, treatment-emergent elevations or worsening of liver tests occurred. Of the three PFIC patients who experienced DILI, two underwent liver transplant.

Obtain baseline liver tests because some PFIC patients have abnormal liver tests at baseline and monitor patients frequently for the first 6 to 8 months, and as clinically needed thereafter, for elevations in liver tests, for the development of liver-related adverse reactions, and for physical signs of hepatic decompensation. If liver test abnormalities or signs of clinical hepatitis occur in the absence of other causes, consider dose reduction or treatment interruption. Permanently discontinue BYLVAY if a patient experiences the following: persistent or recurrent liver test abnormalities, or upon rechallenge, signs and symptoms consistent with clinical hepatitis, or a hepatic decompensation event.

The safety and effectiveness of BYLVAY have not been established in patients with decompensated cirrhosis. Monitor patients with compensated cirrhosis or portal hypertension more frequently and discontinue if hepatic decompensation occurs. IBAT inhibitors, including BYLVAY, are contraindicated in patients with prior or active hepatic decompensation events.

### Diarrhea

In the PFIC clinical trials, diarrhea was reported more frequently in BYLVAY-treated patients compared to placebo. In the PFIC clinical trials, treatment interruption due to diarrhea occurred in 2 patients with 3 events. Treatment interruption due to diarrhea ranged between 3 to 7 days. One patient withdrew from the trial.

If diarrhea occurs, monitor for dehydration and treat promptly. Interrupt 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 treatment.

### Fat-Soluble Vitamin (FSV) Deficiency

Fat-soluble vitamins (FSV) include vitamin A, D, E, and K. PFIC patients can have FSV deficiency at baseline. BYLVAY may adversely affect absorption of FSVs. In clinical trials, new onset or worsening of existing FSV deficiency was reported more frequently in BYLVAY-treated patients compared to placebo.

Obtain baseline INR (International Normalized Ratio) and FSV levels and monitor during treatment along with any clinical manifestations. If FSV deficiency is diagnosed, supplement with FSV. Discontinue BYLVAY if FSV deficiency persists, worsens, or complications occur despite adequate FSV supplementation.

If bone fracture occurs, consider interrupting BYLVAY treatment and supplement with FSV if indicated.

If bleeding occurs, interrupt treatment with BYLVAY. Optimize treatment of FSV deficiency and consider restarting BYLVAY once the patient is clinically stable.

### Adverse Reactions

The most common adverse reactions for BYLVAY in patients with PFIC are diarrhea, liver test abnormalities, vomiting, abdominal pain, and FSV 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

Limited human data on BYLVAY use in pregnant persons are insufficient 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. As BYLVAY may inhibit the absorption of fat-soluble vitamins, which are essential for normal fetal growth and development, monitor pregnant patients for FSV deficiency and increase supplementation as needed. Consider the woman's need for BYLVAY, the potential drug-related risks to the fetus, and the potential adverse outcomes from untreated maternal PFIC.

There is a pregnancy exposure registry that monitors pregnancy outcomes in persons exposed to BYLVAY during pregnancy. Pregnant women exposed to BYLVAY, or their healthcare providers, should report BYLVAY exposure by calling 1-855-463-5127.

**To report SUSPECTED ADVERSE REACTIONS, contact Ipsen Biopharmaceuticals, Inc. at 1-855-463-5127 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.**

**Please see additional Important Safety Information throughout and the full Prescribing Information.**

**References: 1.** BYLVAY. Prescribing Information. Ipsen Biopharmaceuticals, Inc.; 2025.
**2**. Data on file. Ipsen US. [NON-US-004496].