Your PFIC itch-related sleep tracker

Sometimes itch from progressive familial intrahepatic cholestasis (PFIC) doesn't take a break—it may make sleeping difficult, too

In the morning, track how itch affected your or your child's sleep, answering only the relevant questions. This information can help you have a full conversation with your doctor about the impact of itch.

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	SUN	MON	TUE	WED	THUR	FRI	SAT
How bad was scratching since going to bed? (From 0 to 4, where 0 means "no scratching" and 4 means "worst possible scratching.")							
Was there any bleeding or blood on bedsheets in the morning?							
Was a caregiver needed to help your child fall asleep?							
Was soothing needed to fall asleep?							
Did your child need to sleep with a caregiver?							
How many times did you or your child wake up during the night?							
Were any medications taken that could make someone sleepy before bed?							

Bring this to your next doctor appointment to share the full picture of how itch is affecting you or your child

What is Bylvay® (odevixibat)?

Bylvay is a medicine to treat pruritus in 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

• Speak with your healthcare provider if you experience abdominal pain, vomiting, diarrhea, hematoma, decreased weight, or dehydration as these have been reported with the use of Bylvay. Patients should contact their healthcare provider if they experience new onset or worsening of diarrhea



Please see additional <u>Important Safety Information</u> on next page, and the full Prescribing Information.

IMPORTANT SAFETY INFORMATION (CONT'D)

- Elevations in liver tests (for example, AST, ALT, TB) have been observed with use of Bylvay. The patient's healthcare provider will obtain liver tests before starting Bylvay and periodically during treatment with Bylvay. Patients should report to their healthcare provider any symptoms of liver problems (for example, nausea, vomiting, skin or the whites of eyes turn yellow, dark or brown urine, pain on the right side of the abdomen, loss of appetite)
- Bylvay may impair absorption of fat-soluble vitamins (FSV), which include vitamins A, D, E and K (vitamin K is assessed by measuring INR). The patient's healthcare provider will obtain serum levels of vitamins A, D, E, and INR (for vitamin K) at baseline and periodically during treatment to assess for worsening of FSV deficiency
- Do not swallow the 200 mcg or 600 mcg capsule(s) containing Oral Pellets whole. These are intended to be opened and the contents mixed into soft food. Take Bylvay in the morning with a meal
- · For patients taking bile acid binding resins, take Bylvay at least 4 hours before or 4 hours after taking a bile acid binding resin

You are encouraged to report side effects to FDA at 1-800-FDA-1088 or at www.fda.gov/medwatch. You may also report side effects to Ipsen Biopharmaceuticals, Inc. at 1-855-463-5127.

Please see the full **Prescribing Information**.



