

# 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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MM DD MM DD

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

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

Uses

- BYLVAY is a prescription medicine used:
- For the treatment of itching in patients 3 months of age and older with progressive familial intrahepatic cholestasis (PFIC).

Limitation of Use:

BYLVAY might not work for some PFIC type 2 patients who have specific *ABCB11* gene changes. Talk with your healthcare provider if you have questions.

Please see additional [Important Safety Information](#) on next page, and the full [Prescribing Information](#).

## IMPORTANT SAFETY INFORMATION

- You should not use BYLVAY if you have had or have an advanced stage of liver disease. Talk with your healthcare provider if you have any liver conditions.
- Abnormal liver tests have been observed with use of BYLVAY. Liver tests should be obtained before starting and periodically during therapy to monitor for liver injury. Immediately report to your healthcare provider any signs or symptoms of liver injury, such as nausea, vomiting, skin or the whites of eyes turn yellow, dark or brown urine, pain on the right side of the abdomen, or loss of appetite.
- Notify your healthcare provider if you experience new onset or worsening of diarrhea.
- BYLVAY may decrease the absorption of certain vitamins, which include vitamins A, D, E, and K (FSV or fat-soluble vitamins). Your blood levels of these vitamins should be measured before starting and periodically during treatment to assess for FSV deficiency. You may bleed more easily or may bleed longer. Call your healthcare provider if you have any signs or symptoms of bleeding.
- The most common side effects of BYLVAY in patients with PFIC are diarrhea, liver test abnormalities, vomiting, abdominal pain, and 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.
- For patients taking bile acid binding resins, take BYLVAY at least 4 hours before or 4 hours after taking a bile acid binding resin.
- There is a pregnancy safety study that collects outcome data in women taking BYLVAY during pregnancy. Pregnant women exposed to BYLVAY should report if they have used BYLVAY during pregnancy by calling 1-855-463-5127.

**You are encouraged to report side effects to FDA at 1-800-FDA-1088 or at [www.fda.gov/medwatch](http://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](#).**



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