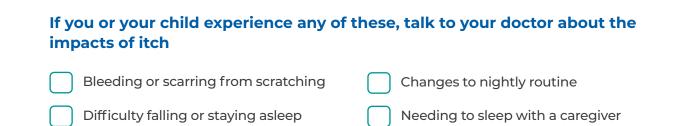
Talking to your doctor about it Ch (pruritus) from PFIC

Itch from progressive familial intrahepatic cholestasis (PFIC) is more than normal itching and may be frequent, deep, and frustrating



Blood on bedsheets from scratching

| ٦ | Needina | medications to sleep | |
|---|---------|----------------------|--|
| | needing | medications to sleep | |

What other ways does itch from PFIC impact daily life for you or your child? Write them down here and share with your doctor.





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





Your PFIC itch tracker

Itch is a common symptom of progressive familial intrahepatic cholestasis (PFIC), and tracking it over time can help you give doctors a full picture of how things are going



____/___--___/___ MM__DD___MM__DD

| SUNDAY | MONDAY | TUESDAY | WEDNESDAY | THURSDAY | FRIDAY | SATURDAY |
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Write down any specific notes (for example, was itch worse at night or during the day?).

Share this with your doctor to keep them informed about how itch is affecting you or your child

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 <u>www.fda.gov/medwatch</u>. You may also report side effects to Ipsen Biopharmaceuticals, Inc. at 1-855-463-5127.



