

Talking to your doctor about **itch** (pruritus) from PFIC

PFIC
Dialogue
Tool

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

If you or your child experience any of these, talk to your doctor about the impacts of itch

- | | |
|---|--|
| <input type="checkbox"/> Bleeding or scarring from scratching | <input type="checkbox"/> Changes to nightly routine |
| <input type="checkbox"/> Difficulty falling or staying asleep | <input type="checkbox"/> Needing to sleep with a caregiver |
| <input type="checkbox"/> Blood on bedsheets from scratching | <input type="checkbox"/> 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.



Signs of itch aren't always obvious

Babies and young kids may

- Rub themselves or rub against objects
- Kick their legs and be restless
- Cry, be irritable and fussy
- Struggle to fall and stay asleep



Older kids and adults may

- Feel embarrassed
- Feel effects on mood
- Struggle to fall asleep, or feel tired

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.

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.

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

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

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

At the end of each day, use the table below to track itch and share the results with your doctor

No scratching



0

A little scratching



1

Medium scratching



2

A lot of scratching



3

Worst possible scratching



4

___/___ - ___/___
MM DD MM DD

SUNDAY	MONDAY	TUESDAY	WEDNESDAY	THURSDAY	FRIDAY	SATURDAY

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)

- 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. You may also report side effects to Ipsen Biopharmaceuticals, Inc. at 1-855-463-5127.

Please see the full [Prescribing Information](#).