

Talking to your child's doctor about PFIC itch

Tracking itch (pruritus) over time can help you give doctors a full picture of how things are going

EXPRESSIONS 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



Rub their eyes and ears

OLDER KIDS AND ADULTS MAY



Feel embarrassed



Feel impacts on self-esteem



Struggle to fall asleep, or feel tired



Get accustomed to their itch



Feel effects on mood

What other ways does itch from PFIC impact daily life for you or your child? You can use this space to write them down along with any specific notes (for example, is itch worse at night or during the day?).

Share this page with your child's doctor to keep them informed about the impact of itch

What is BYLVAY (odevixibat)?

BYLVAY is a prescription medicine:

- For the treatment of itching in patients 3 months of age and older with progressive familial intrahepatic cholestasis (PFIC).

Limitation of Use: BYLVAY is not recommended for some PFIC type 2 patients who have specific *ABCB11* gene changes. Talk with your healthcare provider if you have questions.

What are the possible side effects of BYLVAY?

BYLVAY can cause serious side effects, including:

- 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](#) throughout, and the full [Prescribing Information](#) and [Instructions for Use](#) for BYLVAY.



Your PFIC itch (pruritus) tracker

Itch from PFIC is more than normal itching—it may be frequent, deep, and frustrating

If your child experiences any of these, talk to their doctor about the impact of itch

- | | | |
|---|---|---|
| ☐ Bleeding or scarring from scratching | ☐ Changes to nightly routine | ☐ Difficulty falling or staying asleep |
| ☐ Needing to sleep with a caregiver | ☐ Blood on bedsheets from scratching | ☐ Needing medications to sleep |

At the end of each day, use this table 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 		
WK 1	SUNDAY	MONDAY	TUESDAY	WEDNESDAY	THURSDAY	FRIDAY	SATURDAY
WK 2							

What are the possible side effects of BYLVAY? (cont'd)

BYLVAY can cause serious side effects, including:

- 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, may bleed longer, or experience a bone fracture. Call your healthcare provider if you have any signs or symptoms of bleeding.

The most common side effects of BYLVAY include:

- 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 and contact your doctor immediately.

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 full [Prescribing Information](#) and [Instructions for Use](#) for BYLVAY.



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