

Understanding the basics of **PFIC** and a treatment for it

This guide can help you discuss progressive familial intrahepatic cholestasis, also known as PFIC, and a treatment for it with your doctor, with tips for those conversations if you're not sure what to ask.

PFIC is a spectrum of rare, genetic disorders that can cause liver damage and severe itching.

Asking your doctor about PFIC

How is PFIC affecting my or my child's liver?

Are any tests needed to get a fuller picture of the impact of PFIC?

Do I need to visit other doctors who specialize in liver diseases?



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 [Important Safety Information](#) throughout, and the full [Prescribing Information](#).



Talking to your doctor about **treatment** for itch from PFIC

Ask your doctor



There are different ways of managing PFIC. Ask your doctor to explain



Nutritional supplements



Medications to treat itch



Surgery, liver transplant

Bylvay is an FDA-approved medicine to treat pruritus (itch) in patients with PFIC as young as 3 months of age

Bylvay may not be effective in a subgroup of people with certain PFIC2 variants that result in non-functional or complete absence of the bile salt export pump protein.

Use the questions below as a starting point for talking to your doctor about whether Bylvay is right for you.

Could Bylvay help me or my child with itch from PFIC?

How is Bylvay taken?

How does Bylvay work?

Can Bylvay help with any level of itch?

How soon can results be seen when starting Bylvay?

What side effects can occur when taking Bylvay?

What support is available for people starting Bylvay?

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)



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



Bring this discussion guide to your next appointment to help you have a full conversation with your doctor about itch from PFIC

All images are actor portrayals.

Notes: _____



Talk to your doctor about how itch from PFIC impacts you or your child

IMPORTANT SAFETY INFORMATION (CONT'D)

- 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.

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