

# 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?

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

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

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## 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).

### 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.

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)**

- 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.

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:** \_\_\_\_\_

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

### IMPORTANT SAFETY INFORMATION (CONT'D)

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

