


PFIC
progressive
familial
intrahepatic
cholestasis



My Bylvay doctor discussion guide

Helpful tips and symptom tracking for
better conversations about treatment
for itch from progressive familial
intrahepatic cholestasis (PFIC)

All images are actor portrayals.

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 Important Safety Information throughout and on page 2, and the accompanying full Prescribing Information, also at <https://bylvay.com>.

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



Possible side effects of Bylvay

Understanding the basics of PFIC

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
- 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

This guide can help you understand progressive familial intrahepatic cholestasis (pronounced *koh-luh-stey-sis*), also known as PFIC, and a treatment for itch, with tips for talking to doctors if you're not sure what to ask.

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

Ask your doctor

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?



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

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

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

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



Use the trackers on the next pages to help you talk to your doctors

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)

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Your PFIC **itch tracker**

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

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 impacts on self-esteem

Feel effects on mood

Struggle to fall asleep, or feel tired

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

	No scratching	A little scratching	Medium scratching	A lot of scratching	Worst possible scratching	
						
	0	1	2	3	4	
	SUNDAY	MONDAY	TUESDAY	WEDNESDAY	THURSDAY	FRIDAY
WEEK 1						
WEEK 2						
SATURDAY						

Use this space to 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

Your PFIC itch-related sleep tracker

Sometimes itch doesn't take a break—it may make sleeping difficult, too

In the morning, track how itch affected your or your child's sleep, answering only the relevant questions. This information can help you have a full conversation about the impact of itch with your doctor.

	SUN	MON	TUE	WED	THUR	FRI	SAT
How bad was scratching since going to bed? (From 0 to 4, where 0 means "no scratching" and 4 means "worst possible scratching.")							
Was there any bleeding or blood on bedsheets in the morning?							
Was a caregiver needed to help your child fall asleep?							
Was soothing needed to fall asleep?							
Did your child need to sleep with a caregiver?							
How many times did you or your child wake up during the night?							
Were any medications taken that could make someone sleepy before bed?							

Bring this to your next doctor appointment to share the full picture of how itch is affecting you or your child

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)

- 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

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**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)

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(odevixibat)

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