

PFIC
progressive
familial
intrahepatic
cholestasis



All images are
actor portrayals.

Relieve the itch and
**Preserve
what's
precious**

Learn about PFIC and how
Bylvay can reduce the itch

What is Bylvay® (odevixibat)?

Bylvay is a medicine to treat pruritus (itch) in patients with progressive familial intrahepatic cholestasis (PFIC) as young as 3 months of age.

◦ **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 13, and the full [Prescribing Information](#).

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

Living with

progressive familial intrahepatic cholestasis

If you or your loved one is dealing with progressive familial intrahepatic cholestasis (PFIC), you've already dealt with numerous challenges. This brochure can help you understand PFIC and address a key challenge: finding relief for the distressing itch—or “cholestatic pruritus”—to make the journey a bit more manageable.

What is PFIC?

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

Words to know: Cholestatic pruritus

Your doctor may describe itch using this term. **Cholestatic** (pronounced *koh-luh-stat-ik*) means the flow of bile from the liver is slowed or blocked.

Pruritus (pronounced *proo-rah-y-tuhs*) is a medical term for itching.

PFIC is a progressive disease.

“Progressive” means that PFIC may get worse over time. Itching can be difficult to treat, but **relief may be possible**.



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

More than **75%** experience itch associated with PFIC

Please see [Important Safety Information](#) throughout and on page 13, and the full [Prescribing Information](#).

Living with

progressive familial intrahepatic cholestasis

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

**Disruptions due to the itch from Alagille syndrome can
affect each patient and caregiver differently**

**Make sure to talk to your doctor
about the impact of itch**

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throughout and on page 13, and the full
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The **liver** with PFIC

What happens in a healthy liver?

In a healthy liver, bile acids drain from the liver to the small intestine. Up to 95% of the bile acids are then recycled back to the liver by the IBAT.

Words to know: Bile acids 

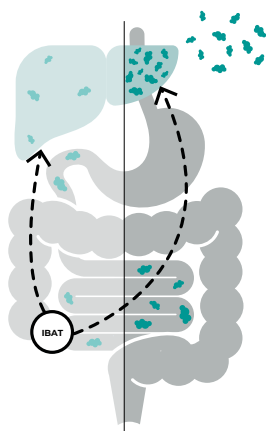
Bile acids are created in the liver to break down food and release the nutrients inside.

Words to know: IBAT 

The ileal bile acid transporter, or IBAT, recycles bile acids back into the liver from the intestines.

How PFIC affects the liver

- 1 Bile acids don't drain properly out of the liver to the small intestine.
- 2 Bile acids build up to a level that may be harmful to the liver.
- 3 Excess bile acids spill into the bloodstream.



The buildup of bile acids in the liver and the bloodstream may be the cause of itch (cholestatic pruritus) in PFIC.

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 [Important Safety Information](#) throughout and on page 13, and the full [Prescribing Information](#).

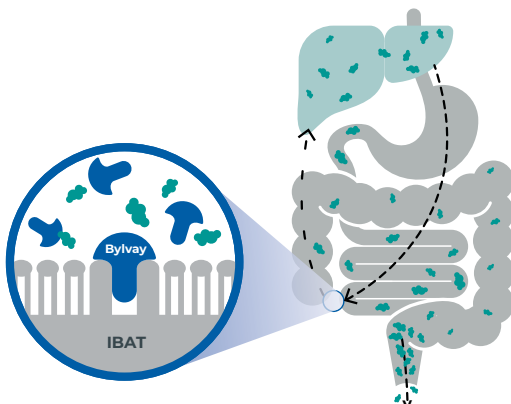
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(odevixibat)
200/400/600/1200 mcg capsules



How does **Bylvay** work?

Bylvay inhibits the IBAT and decreases bile acid recycling back to the liver

These bile acids then leave the body naturally as waste.



While the exact way Bylvay reduces itch isn't fully understood, IBAT inhibition may reduce bile acid buildup as measured by bile acid in the blood.

Ask your doctor if Bylvay can help with itch

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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Get the
relief you're
looking for

Relief for any level of itch

Some people live with itch so long that it feels normal, even though it's not. For others, itch is frustrating and relentless. Bylvay works whether itch is mild or severe.

In the clinical trial for Bylvay:



Scratching was measured on a 5-point scale, with 0 meaning no itch and 4 meaning worst possible scratching.*

- **Less scratching** meant an improvement of 1 point or more
- **Little or no itch** was a score of 0 or 1 on the scale

*Scratching scores were recorded twice daily by a caregiver.

IMPORTANT SAFETY INFORMATION (CONT'D)

- 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

Please see [Important Safety Information](#) throughout and on page 13, and the full [Prescribing Information](#).

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Get the **relief** you're looking for

Early and lasting reduction of itch (cholestatic pruritus) with Bylvay

In a clinical trial of 62 people, Bylvay improved caregiver-reported scratching severity as early as week 4 and sustained through 24 weeks in people with PFIC.

Over 24 weeks, 35% of patients taking Bylvay 40 mcg/kg/day and 30% of patients taking Bylvay 120 mcg/kg/day achieved little or no itch compared with 13% of patients taking placebo. By 48 weeks,*



of Bylvay patients achieved **little or no itch**

Over 24 weeks, 52% of patients taking Bylvay 40 mcg/kg/day and 32% of patients taking Bylvay 120 mcg/kg/day experienced less scratching compared with 11% of patients taking placebo. By 48 weeks,*



of Bylvay patients experienced **less scratching**

*In the extension trial, all 112 enrolled people received 120 mcg/kg/day of Bylvay.

Reduced itch was sustained through 96 weeks

Most common side effects

The most common side effects in Bylvay patients with PFIC were diarrhea, elevations in liver tests, vomiting, abdominal pain, and certain vitamin deficiencies.

Reduce the itch from PFIC with Bylvay

IMPORTANT SAFETY INFORMATION (CONT'D)

- For patients taking bile acid binding resins, take Bylvay at least 4 hours before or 4 hours after taking a bile acid binding resin

Please see [Important Safety Information](#) throughout and on page 13, and the full [Prescribing Information](#).

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Itch-related **sleep disruption** in patients with PFIC

There are limitations to the sleep disruption data, and results should be reviewed with caution. Further testing is required. If you have any questions, your doctor can help explain it further.



After the Bylvay clinical trial ended, a separate analysis was done on caregiver responses to 7 questions about sleep disruption.

Caregivers reported the following

- Days needing soothing from a caregiver to fall asleep
- Days needing to sleep with a caregiver
- Days needing help falling asleep

There were also questions about

- Seeing blood due to scratching
- Number of awakenings
- Days needing to take medications to induce sleep
- Daytime tiredness

IMPORTANT SAFETY INFORMATION (CONT'D)

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Itch-related **sleep disruption** in patients with PFIC

By 72 weeks, Bylvay patients who had ≥ 1 -point improvement in itch score reported*

75%

fewer days
needing
soothing from
a caregiver
to fall asleep

55%

fewer days
needing to
sleep with
a caregiver

76%

fewer days
needing help
falling asleep

*By 24 weeks, patients taking Bylvay experienced 44% fewer days needing soothing from a caregiver to fall asleep compared with 8% taking placebo; 42% fewer days needing to sleep with a caregiver compared with 6% taking placebo; and 43% fewer days needing help falling asleep compared with 3% taking placebo.

**Ask your doctor about itch-related sleep disruption
and the results seen with 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)

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 **Bylvay**
(odevixibat)

200 | 400 | 600 | 1200 mcg capsules



Flexible, once-daily **dosing** to meet your needs

There are options when taking Bylvay

If you are prescribed Bylvay, your doctor determines the right dose based on weight.

Bylvay capsules can be



**Swallowed
whole**



**Opened and mixed with
a small amount of soft,
room-temperature food**



**Opened and mixed
with liquids such as
breast milk, formula,
or water**

Bylvay is also available as Oral Pellets.



**Consider the flexible dosing
options of 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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 **Bylvay**
(odevixibat)

200/400/600/1200 mcg capsules

Flexible, once-daily **dosing** to meet your needs

No added flavor means Bylvay is easy to mix with a morning meal for both kids and adults



Once-daily dosing



Can be taken with a morning meal

No need to delay feeding or mealtimes after dosing—take Bylvay on the regular feeding schedule

For complete instructions on taking Bylvay, download the [Instructions for Use](#).



Click for helpful videos on how to take Bylvay

IMPORTANT SAFETY INFORMATION (CONT'D)

- 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

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What to **know** about side effects

Can Bylvay cause side effects?

Anytime you're considering a new treatment for itch (cholestatic pruritus) from PFIC, it's important to understand the possible risks and benefits. Some patients with PFIC taking Bylvay may experience side effects. If you experience any side effects, you should immediately talk to your doctor.

The most common side effects seen in a clinical study of patients with PFIC were

Abnormal liver tests

Changes in laboratory tests related to the liver. Your doctor will order certain tests to monitor your liver function.

Diarrhea

A mild increase in the frequency of bowel movements or loose, watery stool consistency for typically less than 1 week.

Abdominal pain

Pain in the abdomen (belly).

Vomiting

Throwing up.

Low vitamin levels

Vitamin levels that are lower than normal. Your doctor will order blood tests to measure levels of vitamins and may prescribe supplementation (taking vitamin supplements).

What to do if side effects occur

You should always talk to your doctor first before stopping or changing your Bylvay dose. If you experience side effects, you should immediately talk to your doctor. Your doctor may change the dose or discontinue Bylvay depending on the side effects. Your doctor may recommend restarting Bylvay after the side effects resolve.

You can report side effects to Ipsen Biopharmaceuticals, Inc. at 1-855-463-5127 or to the FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Talk to your doctor about what to expect when starting Bylvay and what to do if you experience side effects

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200|400|600|1200 mcg capsules

Indications and Usage

Bylvay is an ileal bile acid transporter (IBAT) inhibitor indicated for the treatment of cholestatic pruritus in:

- Patients 12 months of age and older with Alagille syndrome (ALGS)
- 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
- 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



Dedicated support

IPSENCARES®
Coverage, Access, Reimbursement & Education Support

IPSEN CARES patient support program can help you get access to your Bylvay® (odevixibat) prescription with the information and support you need.

Your Patient Access Manager (PAM) can

- ✓ Provide information and support to help you prepare to talk to your healthcare provider, specialty pharmacy, and insurance company
- ✓ Work with you to understand your specific situation and healthcare coverage needs
- ✓ Help to identify possible financial support programs for which you may qualify

Your Patient Education Liaison (PEL) can

- ✓ Provide educational information to help you, your family, and your caregivers better understand your condition, access needs, and prescribed treatment expectations
- ✓ Help you to understand your specific situation and healthcare needs based on the direction and advice provided by your healthcare provider
- ✓ Work in connection with your healthcare providers to support you and your caregivers through some of the many challenges of living with your condition



Enrolling in IPSEN CARES is quick and easy. Your healthcare provider must complete the IPSEN CARES Enrollment Form, and you must review and sign the patient authorization section.

To learn more about IPSEN CARES:

[IPSENCARES.com](https://ipsencares.com)

(866) 435-5677

Monday-Friday, 8:00 AM – 8:00 PM ET

support@ipsencares.com

Please see [Important Safety Information](#) throughout and on page 13, and the full [Prescribing Information](#).

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Bylvay helps relieve the itch (pruritus) of PFIC so you

preserve those precious moments

All images are actor portrayals.



Decreased bile acid recycling



Early and lasting reduction of itch



Ask your doctor about itch-related sleep disruption



Easy to mix with food, and no need to delay meals



Dedicated Patient Access Managers for support every step of the way



Most common side effects in Bylvay patients with PFIC were diarrhea, elevations in liver tests, vomiting, abdominal pain, and certain vitamin deficiencies

Ask your doctor about how Bylvay can help relieve the itch

IMPORTANT SAFETY INFORMATION (CONT'D)

- For patients taking bile acid binding resins, take Bylvay at least 4 hours before or 4 hours after taking a bile acid binding resin

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