



All images are
actor portrayals.

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

Learn about Alagille
syndrome and how Bylvay
can reduce the itch

What is Bylvay® (odevixibat)?

Bylvay is a medicine to treat cholestatic pruritus (itch) in patients with Alagille syndrome as young as 12 months of age.

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 Alagille syndrome

If you or your loved one is dealing with Alagille (pronounced *a-luh-jeel*) syndrome (ALGS), you know the journey has its challenges. This brochure can help you understand Alagille syndrome and address a key challenge: finding relief for the distressing itch—or “cholestatic pruritus”—to make the journey a bit more manageable.

What is Alagille syndrome?

Alagille syndrome is a rare genetic disease that causes damage to the liver, and can affect the heart, eyes, skeleton, kidneys, face, and nervous system.

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.

Alagille syndrome is a progressive disease.

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



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

Up to **88%** experience Alagille syndrome itch

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

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Living with

Alagille syndrome

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 or be impacted socially

Feel effects on mood

Struggle to concentrate

Struggle to fall and stay asleep

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**

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

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The **liver** with Alagille syndrome

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 Alagille syndrome affects the liver

1

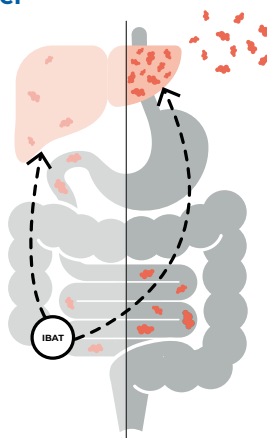
Bile acids don't drain properly out of the liver to the small intestine.

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 Alagille syndrome.

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](#).

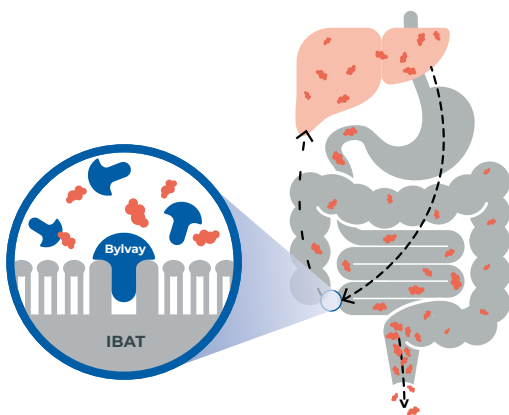
 **Bylvay**
(odevixibat)
200/400/600/1200 mcg capsules



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



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

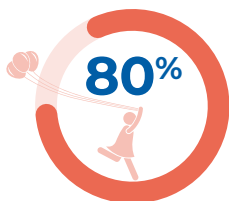
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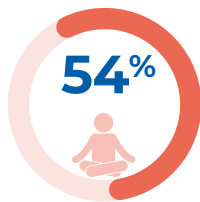
Get the **relief** you're looking for

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

In a clinical trial of 52 people, Bylvay improved caregiver-reported scratching severity as early as week 4 and sustained over 24 weeks in people with Alagille syndrome. By week 24,



experienced **less scratching** with Bylvay compared to 35% taking a placebo



had **little or no** scratching with Bylvay compared to 18% taking a placebo

Reduced itch was sustained through 48 weeks

Most common side effects

The most common side effects in Bylvay patients with Alagille syndrome were diarrhea, abdominal pain, bruising (hematoma), and decreased weight.

Reduce the itch from Alagille syndrome 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](#).

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

Reduced itch may lead to **better sleep**



In the Bylvay clinical trial, caregivers were asked 7 questions about how itch disrupts their child's sleep

In just



the reduced itch (cholestatic pruritus) from Bylvay led to sleep improvements compared to placebo

IMPORTANT SAFETY INFORMATION (CONT'D)

- 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

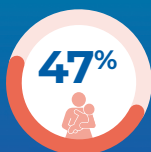
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 **Bylvay**
(odevixibat)

200 | 400 | 600 | 1200 mcg capsules

Reduced itch may lead to **better sleep**

By 24 weeks, Bylvay's itch relief helped patients experience*



fewer days needing soothing from a caregiver to fall asleep compared to 6% taking a placebo



fewer days needing help falling asleep compared to 10% taking a placebo



fewer days needing to sleep with a caregiver compared to 8% taking a placebo

*There were also questions about number of awakenings, days seeing blood due to scratching, days needing to take medication to sleep, and a daytime tiredness score.

The information shown about sleep disruption is a secondary outcome of the study. It was not analyzed to the same extent as the primary outcome about itch. Data should be reviewed with caution. If you have questions about this limitation, your doctor can help explain it further.

**Ask your doctor if less itch with Bylvay
can help you rest easier**

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 Bylway

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

Bylway 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**

Bylway is also available as Oral Pellets.



**Consider the flexible dosing
options of Bylway**

IMPORTANT SAFETY INFORMATION (CONT'D)

- Bylway 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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 **Bylway**
(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

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

 **Bylvay**[®]
(odevixibat)

200 | 400 | 600 | 1200 mcg capsules

What to **know** about side effects

Can Bylvay cause side effects?

Anytime you're considering a new treatment for itch (cholestatic pruritus) from Alagille syndrome, it's important to understand the possible risks and benefits. Some patients with Alagille syndrome 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 Alagille syndrome were:

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).

Bruising (hematoma)

Broken blood vessels that led to blood collecting under the skin.

Weight loss

Change in how much patients weighed. Your doctor will monitor your weight.

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 1-855-252-4736 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

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

 **Bylvay**
(odevixibat)
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://www.ipsencares.com)

(866) 435-5677

Monday-Friday, 8:00 AM – 8:00 PM ET

support@ipsencares.com

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 **Bylvay®**
(odevixibat)

200|400|600|1200 mcg capsules



All images are actor portrayals.

Bylvay helps relieve the itch (cholestatic pruritus) of Alagille syndrome so you

preserve those precious moments



**Decreased bile
acid recycling**



**Early and lasting
reduction of itch**



**Less sleep disruption
with reduced itch**



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



**Dedicated Patient
Access Managers
for support every step
of the way**



**The most common
side effects in Bylvay
patients with Alagille
syndrome were diarrhea,
abdominal pain,
bruising (hematoma),
and decreased weight**

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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