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 prescription medicine for the treatment of itching in patients 12 months of age and older with Alagille syndrome (ALGS).

What are the possible side effects of BYLVAY?

BYLVAY can cause serious side effects, including:

- You should not use BYLVAY if you have or have had an advanced stage of liver disease. Talk with your healthcare provider if you have any liver conditions.

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-**rahy**-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

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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

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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

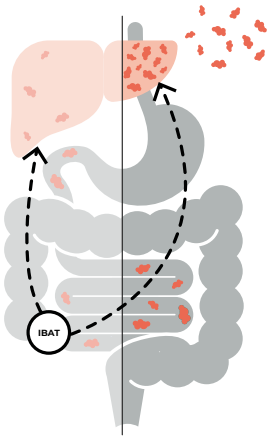
Bile acids are created in the liver to break down food and release the nutrients inside.

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.

What are the possible side effects of BYLVAY? (cont'd)

BYLVAY can cause serious side effects, including:

- 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.

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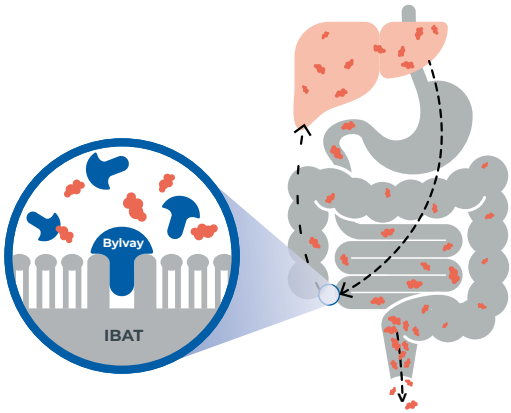
How does Bylvay work?

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

What are the possible side effects of BYLVAY? (cont'd)

BYLVAY can cause serious side effects, including:

- Notify your healthcare provider if you experience new onset or worsening of diarrhea.

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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.

What are the possible side effects of BYLVAY? (cont'd)

BYLVAY can cause serious side effects, including:

- 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 FSV deficiency. You may bleed more easily, may bleed longer, or experience a bone fracture. Call your healthcare provider for any signs or symptoms of bleeding.

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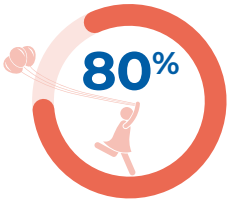
Get the **relief** you're looking for

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

What are the possible side effects of BYLVAY? (cont'd)

The most common side effects of BYLVAY include:

- The most common side effects of BYLVAY treatment in patients with ALGS are diarrhea, abdominal pain, abnormal bleeding, such as bruising, and decreased weight.

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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

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 further.

In just 1 month **the reduced itch (cholestatic pruritus) from Bylvay led to sleep improvements compared to placebo**

What are the possible side effects of BYLVAY? (cont'd)

The most common side effects of BYLVAY include:

- 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.

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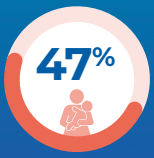
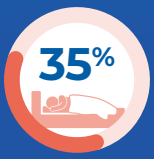
Reduced itch may lead to better sleep

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.

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

What are the possible side effects of BYLVAY? (cont'd)

The most common side effects of BYLVAY include:

- 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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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

What are the possible side effects of BYLVAY? (cont'd)

The most common side effects of BYLVAY include:

- 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 and contact your doctor immediately.

Please see Important Safety Information throughout and on page 13, and the full Prescribing Information.

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

What is BYLVAY (odevixibat)?

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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 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 1-855-463-5127 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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The most common side effects of BYLVAY include:

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- 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.
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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.

Please see full Prescribing Information and Instructions for Use for BYLVAY.

Bylvay® (odevixibat)
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Dedicated support

IPSEN CARES®
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
(866) 435-5677
Monday-Friday, 8:00 AM – 8:00 PM ET
support@ipsencares.com

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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

Please see Important Safety Information throughout and on page 13, and the full Prescribing Information.

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