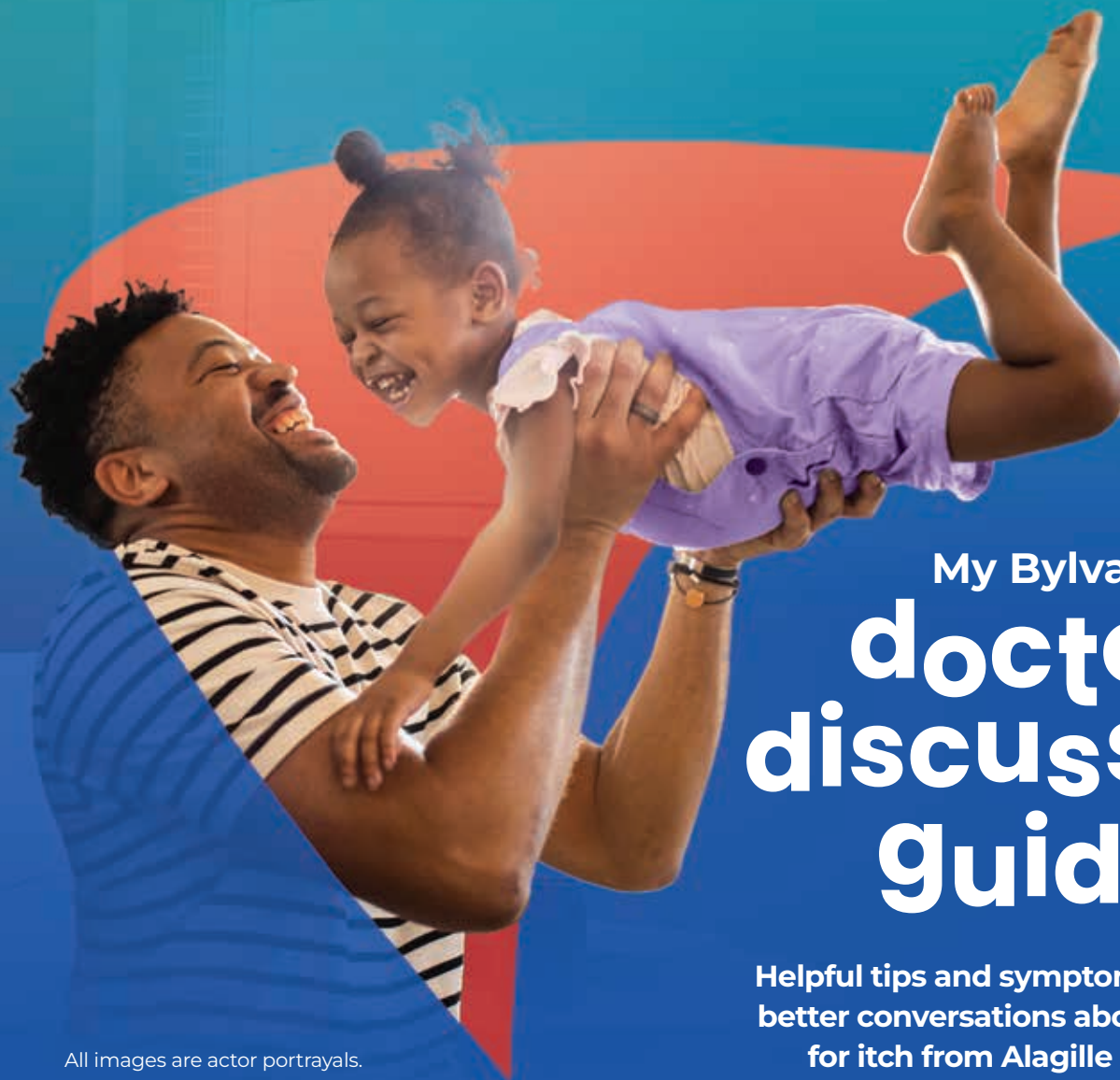


Alagille
syndrome



All images are actor portrayals.

My Bylvay doctor discussion guide

Helpful tips and symptom tracking for
better conversations about treatment
for itch from Alagille syndrome

What is Bylvay® (odevixibat)?

Bylvay is a medicine to treat cholestatic pruritus in patients 12 months of age and older with Alagille syndrome.

Uses

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

IMPORTANT SAFETY INFORMATION

- 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 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

Uses

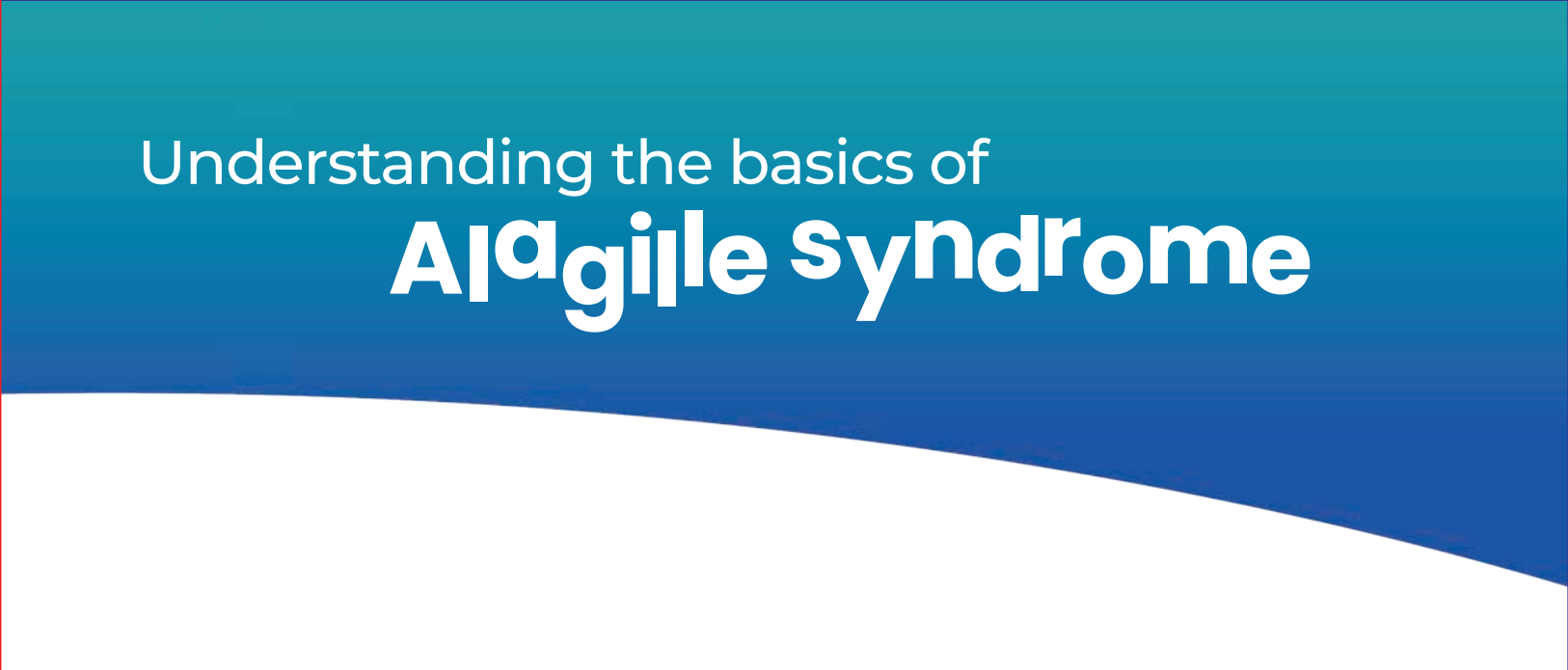
BYLVAY is a prescription medicine used for the treatment of itching in patients 12 months of age and older with Alagille syndrome (ALGS).

IMPORTANT SAFETY INFORMATION

- 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.
- 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 FSV deficiency. You may bleed more easily or may bleed longer. Call your healthcare provider for any signs or symptoms of bleeding.
- The most common side effects of BYLVAY treatment in patients with ALGS are diarrhea, abdominal pain, abnormal bleeding, such as bruising, and decreased weight.
- 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. You may also report side effects to Ipsen Biopharmaceuticals, Inc. at 1-855-463-5127.

Please see full Prescribing Information.



Understanding the basics of Alagille syndrome

This guide can help you understand Alagille (pronounced *a-luh-jeel*) syndrome, also known as ALGS, and a treatment for itch, with tips for talking to doctors if you're not sure what to ask.

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.

Ask your doctor

How is Alagille syndrome affecting my or my child's liver and other parts of the body?

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

Do I need to visit other doctors who specialize in parts of the body affected by Alagille syndrome?



Talking to your doctor about itch (cholestatic pruritus) from Alagille syndrome

Itch from Alagille syndrome 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 Alagille syndrome 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)

- 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.

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Your Alagille syndrome 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 or be impacted socially

Feel effects on mood

Struggle to concentrate

Struggle to fall and stay asleep

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						

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 Alagille syndrome 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 Alagille syndrome

Ask your doctor

There are different ways of managing Alagille syndrome. Ask your doctor to explain



Nutritional
supplements



Medications
to treat itch



Surgery,
liver transplant

Bylvay is an FDA-approved medicine to treat cholestatic pruritus (itch) in patients with Alagille syndrome as young as 12 months of age

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 Alagille syndrome?

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 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 or may bleed longer. Call your healthcare provider for any signs or symptoms of bleeding.

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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 Alagille syndrome**

All images are
actor portrayals.

Notes: _____



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

IMPORTANT SAFETY INFORMATION (CONT'D)

- The most common side effects of BYLVAY treatment in patients with ALGS are diarrhea, abdominal pain, abnormal bleeding, such as bruising, and decreased weight.
- 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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 **Bylvay[®]**
(odevixibat)
200 | 400 | 600 | 1200 mcg capsules