

Understanding the basics of **Alagille syndrome** and a treatment for it

This guide can help you discuss Alagille (pronounced *a-luh-jeel*) syndrome, also known as ALGS, and a treatment for itch with your doctor, with tips for those conversations 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.

Asking your doctor about Alagille syndrome

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?



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 additional [Important Safety Information](#) throughout, and the full [Prescribing Information](#).

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

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)

- 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.

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

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All images are actor portrayals.

Bring this discussion guide to your next appointment to help you have a full conversation with your doctor about itch from Alagille syndrome

Notes: _____



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

IMPORTANT SAFETY INFORMATION (CONT'D)

- 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 additional [Important Safety Information](#) throughout, and the full [Prescribing Information](#).



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