Alagille Syndrome Dialogue Tool

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

Itch from Alagille syndrome is more than normal itching and 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
- ☐ Difficulty falling or staying asleep
- ☐ Blood on bedsheets from scratching
- ☐ Changes to nightly routine
- ☐ Needing to sleep with a caregiver
- ☐ 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.

_____

_____

_____

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

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

Please see additional Important Safety Information throughout, and the full Prescribing Information and Instructions for Use for BYLVAY.

Bylvay® (odevixibat)

200 | 400 | 600 | 1200 mcg capsules

Your Alagille syndrome **itch tracker**

Itch is a common symptom of Alagille syndrome, and tracking it over time can help you give doctors a full picture of how things are going

At the end of each day, use the table below to track itch and share the results with your doctor

___ /___ - ___ /___
MM DD MM DD

SUNDAY	MONDAY	TUESDAY	WEDNESDAY	THURSDAY	FRIDAY	SATURDAY

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

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.
- 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 and contact your doctor immediately.

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.

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