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

Bleeding or scarring from scratching	Changes to nightly routine
Difficulty falling or staying asleep	Needing to sleep with a caregiver
	Needing medications to sleep
Blood on bedsheets from scratching What other ways does itch from Ala	agille syndrome impact daily life for
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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

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.



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

No scratching

A little scratching

Medium scratching

A lot of scratching

Worst possible scratching











2



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

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.
- 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.

