

Please see Important Safety Information

throughout and full Patient Information.



ALL ABOUT LIVMARLI

What does LIVMARLI treat?

LIVMARLI is the **only FDA-approved medicine for cholestatic pruritus (itch)** in patients with Alagille syndrome who are 1 year of age and older.

What does LIVMARLI do?

The goal of LIVMARLI is to provide **lasting itch relief**. LIVMARLI reduces the amount of bile acids in the body. In a clinical study, people that had less bile acid buildup also had less itchiness.



IMPORTANT SAFETY INFORMATION (cont'd)

What are the possible side effects of LIVMARLI?

Changes in liver tests may be a sign of liver injury and can be serious. Your health care provider should do blood tests before starting and during treatment to check your liver function. Tell your health care provider right away if you get any signs or symptoms of liver problems, including:

- nausea or vomiting
- skin or the white part of the eye turns yellow
- dark or brown urine
- pain on the right side of the stomach (abdomen)
- loss of appetite

RESULTS WITH LIVMARLI

How was LIVMARLI studied?

People with Alagille syndrome were treated with LIVMARLI in a **2-part clinical study**. The first part lasted 1 year. During the first year, all participants were given LIVMARLI, except for during a 4-week period in which they were randomly given LIVMARLI or a placebo. In the second part, which didn't include placebo, all participants received LIVMARLI and had the option to **stay on treatment for up to 4 years total**.

During the first year of the study, **84%** of people with Alagille syndrome **experienced less itchiness** than they felt at the start of treatment.

How quickly does LIVMARLI work?

Improvement in itch may be felt **as early as 3 weeks** after starting LIVMARLI, but full results may take 3 to 4 months.

How long will LIVMARLI work for?

Everyone's experience is different. However, patients who continued to take LIVMARLI after the first year (during the long-term part of the clinical study) experienced **minimal to no itch** for the vast majority of days on treatment.



ONCE-DAILY DOSING

How is LIVMARLI taken?

Take LIVMARLI **once daily**, 30 minutes before the first meal of the day, directly from the measuring device delivered with your medicine.

How much LIVMARLI should be taken?

The amount of medicine needed depends on your or your child's weight. Therefore, the prescribed dose may change over time. Be sure to ask your doctor or pharmacist if you have any questions about measuring the medicine correctly. Never change your or your child's dose unless your doctor tells you to.

What does LIVMARLI taste like?

LIVMARLI is a grape-flavored liquid medicine.

What if someone doesn't like taking liquid medicines?

Here are a couple of tips:

- Take the right aim. Use the measuring device that comes with LIVMARLI to squirt the medicine into the inside of the cheek for minimal contact with taste buds
- Add a flavorful twist. Suck on fruit (eg, an orange or lemon) to mask the taste

IMPORTANT SAFETY INFORMATION (cont'd)

What are the possible side effects of LIVMARLI?

Stomach and intestinal (gastrointestinal) problems. LIVMARLI can cause stomach and intestinal problems, including diarrhea, stomach pain, and vomiting during treatment. Tell your health care provider right away if you have any of these symptoms more often or more severely than normal for you.

POSSIBLE SIDE EFFECTS

Are there side effects with LIVMARLI?

It's possible to have side effects while taking LIVMARLI.

LIVMARLI works in the gut, with limited absorpotion into the bloodstream. Because of this, stomach and intestinal (gastrointestinal) side effects are common. Other common side effects may include changes in liver tests, fat-soluble vitamin (FSV) deficiency, bone fractures, and gastrointestinal bleeding. These are not all the possible side effects of LIVMARLI.

It's normal to be concerned about side effects when starting a new medicine, and everyone's experience is different. If you have gastrointestinal problems or other side effects while taking LIVMARLI, talk to your doctor for medical advice. Your doctor may change your dose or temporarily or permanently stop treatment with LIVMARLI if you have certain side effects.

You may also report side effects to the FDA at 1-800-FDA-1088.



IMPORTANT SAFETY INFORMATION (cont'd)

What are the possible side effects of LIVMARLI?

A condition called **Fat Soluble Vitamin (FSV) Deficiency** caused by low levels of certain vitamins (vitamins A, D, E, and K) stored in body fat. FSV deficiency is common in patients with Alagille syndrome but may worsen during treatment. Your health care provider should do blood tests before starting and during treatment.



TIPS FOR CERTAIN SIDE EFFECTS

What steps can be taken if side effects occur

As always, if you're experiencing side effects when taking LIVMARLI, or if your symptoms worsen, contact your doctor or health care team. You may want to share whether you were experiencing them before starting treatment, and if so, make note of how they've changed now that you're taking LIVMARLI.

If you do experience side effects with LIVMARLI, your doctor may suggest taking these steps:

Nausea, vomiting, loose stools, or diarrhea

- **Do** drink plenty of clear liquids, such as water, to prevent dehydration
- **Do** eat foods that are gentle on your stomach. Many people find that clear broth and/or toast help with nausea or vomiting, while dairy and/or concentrated sweets may worsen gastrointestinal symptoms
- Do not exercise immediately after eating

Abdominal pain

• **Do** talk to your doctor for medical advice about abdominal pain

Call your health care provider for medical advice about side effects. You may also report side effects to the FDA at 1-800-FDA-1088.

IMPORTANT SAFETY INFORMATION (cont'd)

What are the possible side effects of LIVMARLI?

Other common side effects reported during treatment were bone fractures and gastrointestinal bleeding.

Tell your health care provider about all medicines that you take. LIVMARLI may affect the way some other medicines work, and some other medicines may affect the way LIVMARLI works. If you take a medicine that lowers cholesterol by binding bile acids, such as cholestyramine, colesevelam, or colestipol, take it at least 4 hours before or 4 hours after you take LIVMARLI.

LIVMARLI is taken by mouth, 1 time each day, 30 minutes before the first meal of the day. Be sure to use the provided oral dosing dispenser to accurately measure the dose of medicine.

TIPS FOR CERTAIN SIDE EFFECTS (CONT'D)

Should treatment with LIVMARLI stop if side effects occur?

It depends. Your doctor might choose to pause treatment or reduce your LIVMARLI dose if you are experiencing certain side effects. If treatment is paused, your doctor may recommend restarting LIVMARLI at a lower dose and slowly increasing it until you can tolerate it. You should never adjust your dose without speaking to a health care provider.



IMPORTANT SAFETY INFORMATION (cont'd)

What are the possible side effects of LIVMARLI?

These are not all of the possible side effects of LIVMARLI. Call your health care provider for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.





Will insurance cover LIVMARLI?

MAP works hand in hand with your doctor and insurance plan on obtaining coverage for LIVMARLI. LIVMARLI is covered by most major insurance plans and nearly all patients pay \$10 or less per fill.*

Once you or your child are prescribed LIVMARLI, MAP experts will help you navigate your insurance coverage and share financial support options that may help with out-of-pocket costs.

What if there's a disruption in insurance coverage?

If you are uninsured or coverage is denied, the MAP team will determine your eligibility for the Mirum Patient Assistance Program (PAP). Mirum PAP allows you to receive LIVMARLI for free for up to 1 calendar year.[†]

What else does MAP have to offer?

MAP is a support program designed to be there for you when and where you need it. In addition to financial support, it includes the following services:

- A MAP Navigator to serve as your main point of contact for answering questions and providing helpful resources
- A MAP Coordinator will work closely with your doctor's office and insurance plan to manage the insurance coverage process for you
- Coordinated delivery to ship LIVMARLI straight to your doorstep overnight
- 24/7 pharmacist access to answer your questions about LIVMARLI
- Educational resources
- MAP Mobile, a convenient text messaging service that makes communicating with MAP even easier
- And more!

It's easy! Just text ENROLL to 833-MAP-4YOU (833-627-4968) to sign up. You can also visit <u>LIVMARLI.com</u> for more information.

*Access as of June 2022. Exceptions apply for some patients, including those with TRICARE insurance.
†Subject to program terms and conditions.



