



DISCOVER  
 **Livmarli**<sup>®</sup>  
(maralixibat) oral solution or tablets

Navigating an Alagille syndrome diagnosis can be hard. Finding ways to manage the condition can be even harder.

This brochure will discuss an FDA-approved medication that targets one of the underlying causes of liver-related problems in Alagille syndrome.

Explore real patient stories



Meet Emma



Meet Finley

Meet Emma on [page 18](#) and Finley on [page 19](#): 2 people who take LIVMARLI to help treat cholestatic pruritus in Alagille syndrome.

**IMPORTANT SAFETY INFORMATION** (cont'd)

**What are the possible side effects of LIVMARLI (maralixibat) oral solution and tablets?**

- **Liver injury.** These changes may be a sign of liver injury and can be serious. Your health care provider should do blood tests and physical exams 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
  - your skin or the white part of your eye turns yellow
  - dark or brown urine
  - pain on the right side of your stomach (abdomen)
  - fullness, bloating, or fluid in your stomach area (ascites)
  - loss of appetite
  - bleeding or bruising more easily than normal, including vomiting blood

Please see additional Important Safety Information for LIVMARLI throughout and full [Prescribing Information](#), including [Patient Information and Instructions for Use](#).

Table of Contents

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## What Can You Find In This Informational Guide?

**4-5**      The liver and cholestatic pruritus

**6-7**      Impact of cholestatic pruritus

**8**         How does LIVMARLI work?

**9**         Early relief with long-term impact

**10-11**     About the ICONIC study

**12-13**     Studies on additional benefits over time

**14-15**     Long-term impact to the liver

**16**         What are the possible side effects?

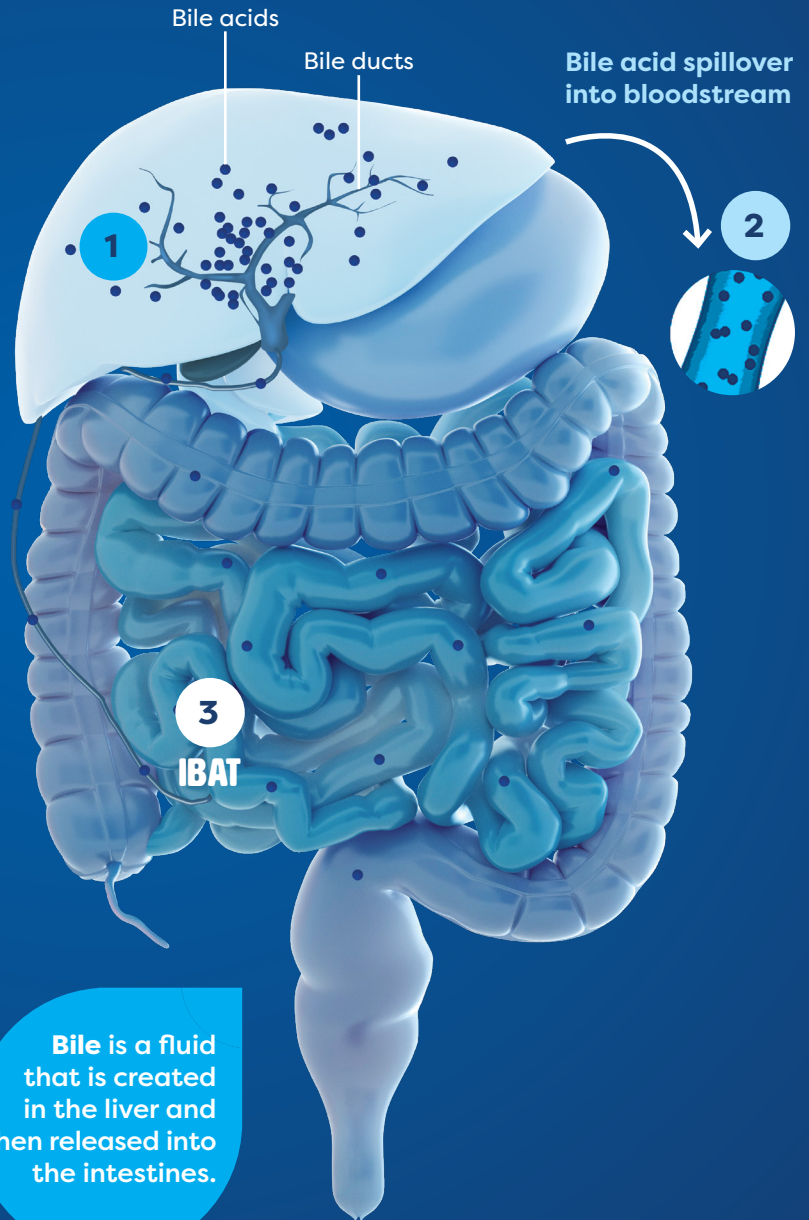
**17**         How is LIVMARLI taken?

**18-19**     Meet others with Alagille syndrome

**20-21**     Mirum Access Plus

# The liver and cholestatic pruritus (itch)

How does Alagille syndrome affect the liver and cause cholestatic pruritus?



**1** People with Alagille syndrome have too few or malformed bile ducts, which **prevents bile from flowing out of the liver.**

**2** When bile is not flowing out of the liver, **bile acids—a part of bile—build up in the liver and the blood.**

**3** 95% of bile acids made by the liver are **recycled in the intestine through the ileal bile acid transporter (IBAT) and go back to the liver.**

**Bile is a fluid that is created in the liver and then released into the intestines.**

Bile acid buildup may cause **immediate problems (cholestatic pruritus [itch])** and have **long-term impacts (liver problems)**.

Over time, the buildup of bile acids can lead to long-term problems, including:

Inflammation  
in the liver



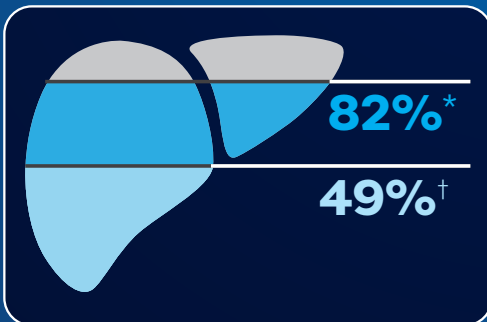
Liver damage  
that worsens  
over time



Scar tissue  
in the liver



Risk of  
transplant



In the past, there were limited treatment options for cholestatic pruritus in Alagille syndrome. As a result, burdensome symptoms like the itch and the damage caused by **bile acid buildup often led to surgery or liver transplant** being used as treatment.

Persistent cholestatic pruritus was a reason in **49%** and **82%** of liver transplants in patients with Alagille syndrome.\*†

\*A retrospective review assessing information of 163 children with Alagille syndrome and liver involvement between 1960 and 2000 found that among the 44 patients who received a liver transplant, refractory (persistent despite treatment) pruritus was a reason in 36 patients (82%); xanthomas (deposits of fat under the skin) that affect appearance were a reason in 32 patients (73%), bone fractures in 15 patients (34%); and/or signs of end-stage liver disease in 5 patients (11%).

†A multicenter retrospective (looking back in time) study of 1433 children with Alagille syndrome assessed outcomes in 1184 of those children who presented with neonatal cholestasis. Among the 328 patients who received a liver transplant and had recorded reasons (some patients had more than 1 reason), intractable (persistent) pruritus was listed as a reason in 161 cases (49%). There were 235 cases of ≥1 complication of persistent cholestasis (72%); of these, growth failure was a reason in 127 cases (54%); xanthomas in 116 cases (49%); metabolic bone disease in 16 cases (7%); fat-soluble vitamin deficiency in 3 cases (1%).

## Impact of cholestatic pruritus (itch)

Cholestatic pruritus is often a very challenging symptom for people with Alagille syndrome, beyond the scratching. It can be difficult to navigate the itch without the right support. Signs and symptoms related to the itch can look different during the day and/or night, vary among patients, or even change with age.



- » 53% of people with Alagille syndrome report difficulty falling asleep due to cholestatic pruritus, while 59% report difficulties staying asleep
- » These sleep disturbances due to cholestatic pruritus are associated with fatigue

Additional signs and symptoms related to cholestatic pruritus can include:



Burning, tingling,  
or pricking  
sensation



Irritability



Rubbing of  
the feet



Skin  
damage



Physical  
discomfort



Inability  
to focus

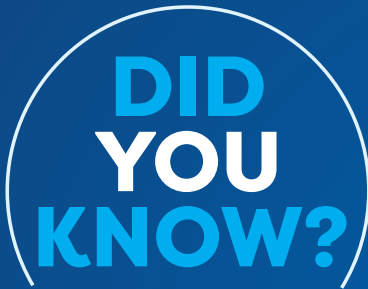


Visit [LIVMARLI.com/between-the-fines](https://LIVMARLI.com/between-the-fines)

to hear from real people with cholestatic pruritus.

## All levels of cholestatic pruritus (itch) deserve attention

Share your experience with cholestatic pruritus with your doctor and let them know about any changes in symptoms.



### Normalization and minimization

- » Symptoms of cholestatic pruritus may start to seem normal or become routine over time. **This can make cholestatic pruritus easier to downplay or minimize**

### Flare-ups

Cholestatic pruritus may only happen occasionally or may get worse during certain times of the year. Some people refer to **times when cholestatic pruritus is worse as “flare-ups.”**

### Easy to mistake

Cholestatic pruritus can be **mistaken for other common causes of itch**, such as:



Change of seasons



Skin conditions that may cause itch



Reactions to possible irritants, like laundry soap



Allergies

## How does LIVMARLI work to reduce cholestatic pruritus (itch) in the body?

1

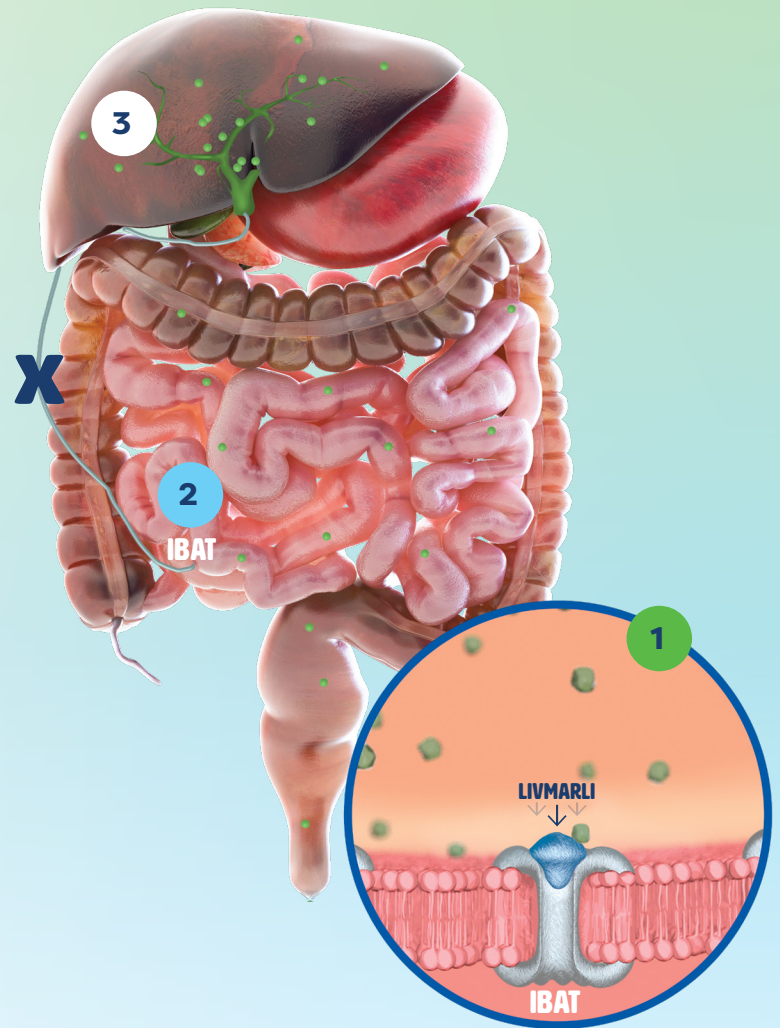
LIVMARLI targets and temporarily blocks something called the ileal bile acid transporter (IBAT). In doing so, LIVMARLI lowers bile acids in the body (as measured by levels in the blood).

2

LIVMARLI blocks bile acids from going back into the liver and increases the amount of bile acids removed from the body in feces.

3

In the clinical study for LIVMARLI, reductions in bile acid buildup were associated with decreases in intensity of cholestatic pruritus.



The way LIVMARLI improves cholestatic pruritus is not completely known. It may involve inhibition of the IBAT, which interrupts bile acid recycling to the liver and decreases serum bile acids.

### IMPORTANT SAFETY INFORMATION (cont'd)

#### What are the possible side effects of LIVMARLI (maralixibat) oral solution and tablets?

- **Stomach and intestinal (gastrointestinal) problems.** LIVMARLI can cause stomach and intestinal problems, including diarrhea and stomach pain during treatment. Diarrhea can also cause the loss of too much body fluid (severe dehydration). Your health care provider may advise you to monitor for new or worsening stomach problems, including stomach pain, diarrhea, blood in your stool, or vomiting.

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## Early relief with long-term impact

The **ONLY** IBAT inhibitor medicine with **7 YEARS** of treatment data in Alagille syndrome.

In a 48-week clinical study called ICONIC, 31 patients with Alagille syndrome were treated with LIVMARLI to find out if it helped reduce levels of cholestatic pruritus (itch) and bile acids in the blood. After 48 weeks, patients had the option to continue the study for up to 4 years.



### Relief through the first year

About 8 in 10 patients saw a big improvement in cholestatic pruritus\* during their first year on treatment.

For many patients taking LIVMARLI, itch relief was seen at the very first assessment (Week 3).



### Reductions in serum bile acid (sBA) levels

About 8 in 10 patients had their sBA levels reduced by at least 20%.<sup>†</sup>



### Improvements up to 7 years

About 14 of 16 patients (88%) who were still taking LIVMARLI in a long-term study saw their cholestatic pruritus improvements persist at 7 years.<sup>‡</sup>



Over the last 7+ years, LIVMARLI has been used by 1500+ patients to treat cholestatic pruritus.<sup>§</sup>

IBAT=ileal bile acid transporter.

\*Defined as an improvement in Itch Reported Outcome (Observer) (ItchRO[Obs]) score of 1 or more. ItchRO(Obs) is a tool designed to measure itch severity over time based on a 5-point scale.

<sup>†</sup>24 of 29 patients (83%) experienced reductions in sBA during the 48-week period of the ICONIC study.

<sup>‡</sup>Based on data from MERGE, which evaluated results from 3 clinical studies to determine how long-term treatment affected cholestatic pruritus. These included data from 86 patients, including 23 who stayed on treatment for 7 years.

<sup>§</sup>Estimation includes clinical studies, early access program, and commercial treatment. Not all patients taking LIVMARLI will have the same experiences.

### IMPORTANT SAFETY INFORMATION (cont'd)

#### What are the possible side effects of LIVMARLI (maralixibat) oral solution and tablets?

- **Stomach and intestinal (gastrointestinal) problems.** Tell your health care provider right away if you have any new or worsening signs or symptoms of stomach and intestinal problems, including:
  - diarrhea
  - vomiting
  - more frequent bowel movements than usual
  - urinating less often than usual
  - stools that are black, tarry, or sticky, or have blood or mucous
  - dizziness
  - severe stomach-area pain or tenderness
  - headache

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## About the ICONIC study

ICONIC was a 48-week, multicenter study with a 4-week, double-blind, placebo-controlled period, meaning the study was run in many locations, and patients and doctors were not aware which patients received LIVMARLI and which received placebo.\*



Patients were included if they were between 1 and 18 years old, diagnosed with Alagille syndrome, had serum bile acid (sBA) levels more than 3 times the highest level considered normal, and had moderate (or worse) cholestatic pruritus (itch).

**All 31 patients in the study received LIVMARLI for 18 weeks, at which point some were switched to placebo.**

For those taking placebo, symptoms of **cholestatic pruritus returned and bile acid levels rose within 4 weeks.**



**At Week 23, all patients went back to taking LIVMARLI, and their symptoms and bile acid levels improved.**

\*Placebo looked and tasted like a “real” treatment but did not have any active medicine.

### IMPORTANT SAFETY INFORMATION (cont'd)

#### What are the possible side effects of LIVMARLI (maralixibat) oral solution and tablets?

- A condition called **Fat-Soluble Vitamin (FSV) Deficiency caused by low levels of certain vitamins (vitamin 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, and may monitor for bone fractures and bleeding, which are common side effects.

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## The ItchRO scale

In the clinical study, patients kept an ongoing log of their itch using the **Itch Reported Outcome (ItchRO) tool**. This tool was used to measure itch severity over time based on a 5-point scale:



0 Not itchy at all



1 A little bit itchy

2 Somewhat itchy

3 Very itchy



4 Extremely itchy

Changes in ItchRO score of 1 point or more represent noticeable differences in cholestatic pruritus (itch), and doctors see them as “clinically meaningful.”



## Long-term data

Patients in the ICONIC study had the option of staying on LIVMARLI long term (up to 4 years). 23 patients entered the long-term part of the study, 15 of whom are included in the 4-year results.

### IMPORTANT SAFETY INFORMATION (cont'd)

Tell your health care provider about all medicines that you take, as LIVMARLI may interact with other medicines. If you take a medicine that lowers cholesterol by binding bile acids, such as cholestyramine, colesevelam, or colestipol, take LIVMARLI at least 4 hours before or 4 hours after you take that medicine.

Your health care provider may change your dose, or temporarily or permanently stop treatment if you have certain side effects.

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# What study data tell us about additional benefits over time

## The MERGE study background

A long-term study called MERGE followed up with 86 patients from 3 separate clinical studies: ICONIC, IMAGINE, and IMAGINE-II to evaluate the efficacy and safety of LIVMARLI over time in people with Alagille syndrome. The study included data from 23 patients who remained on treatment for 7 years.\*†

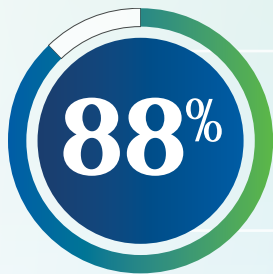
### MERGE assessed changes in:

- » Cholestatic pruritus (itch)
- » Serum bile acids (sBAs)
- » Growth (height and weight)
- » Bilirubin levels
- » Liver enzymes—alanine aminotransferase (ALT) and aspartate aminotransferase (AST)

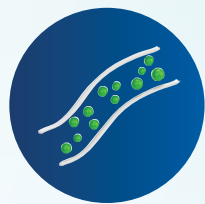
\*MERGE was a multicenter, open-label study, meaning the study was run in many locations, and patients and doctors were aware of the treatment being given. Some people chose to keep taking LIVMARLI long term because they felt it was helping them, even if they did not meet the study's formal measures showing improvement in cholestatic pruritus.

†ICONIC was a 48-week study of 31 patients. IMAGINE and IMAGINE-II were 72-week studies that included 53 patients.

## Results at 7 years



**14 out of 16 patients** who had experienced cholestatic pruritus improvements after starting LIVMARLI still **felt significant relief**‡



### sBA reductions

#### The importance of sBA levels

sBA refers to the level of bile acid in a person's blood. High levels of bile acids in the body are associated with cholestatic pruritus. In Alagille syndrome, this bile acid buildup may also result in liver injury.



**Overall, the 23 patients who continued LIVMARLI for up to 7 years saw improvements in sBA levels**

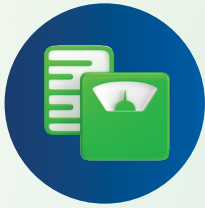
‡Improvements in cholestatic pruritus defined as a reduction in Itch Reported Outcome (ItchRO) score of 1 or more. ItchRO is a tool designed to measure itch severity over time based on a 5-point scale. A total of 23 patients were evaluated for cholestatic pruritus improvements at 7 years.

### IMPORTANT SAFETY INFORMATION (cont'd)

LIVMARLI is available in oral solution and tablet formulations. LIVMARLI is taken by mouth, 1 time each day, 30 minutes before a meal in the morning. For the oral solution, be sure to use the provided oral dosing dispenser to accurately measure the dose of medicine.

These are not all of the possible side effects of LIVMARLI. For more information, ask your health care provider or pharmacist. Call your doctor for medical advice about side effects. You may report side effects to the FDA at 1-800-FDA-1088.

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## Changes in growth (height and weight)

Results from the MERGE study show that **patients who saw a reduction in cholestatic pruritus (itch) were also more likely to grow and gain weight over time.**

Height and weight in MERGE were measured as a **Z-score, which shows how someone compares with the average** for their age and sex.

**Patients grew taller and gained weight within the first year of treatment with LIVMARLI. Improvements in both height and weight continued through 7 years.\***

\*A total of 23 patients remained on treatment at Year 7.

## How LIVMARLI affected bilirubin, ALT, and AST

Doctors measure bilirubin, ALT, and AST to detect, monitor, and understand the severity of liver injury or disease.

- » **Bilirubin** is a part of bile that forms when your body breaks down red blood cells. If bile is not flowing properly, bilirubin can build up in the blood
- » **ALT and AST** are liver enzymes that help process proteins and are used as an indicator of liver health. When liver cells are damaged or inflamed, these enzymes can leak into the bloodstream, causing higher levels of ALT and AST in the blood



## Lower bilirubin levels were seen through 7 years of treatment with LIVMARLI.

Reductions were seen in both total bilirubin (all bilirubin in your blood) and direct bilirubin (bilirubin that your liver processed to exit your body).

**No significant changes were seen in ALT or AST from the start of treatment in patients taking LIVMARLI.**

ALT=alanine aminotransferase; AST=aspartate aminotransferase.

## IMPORTANT SAFETY INFORMATION (cont'd)

### What are the possible side effects of LIVMARLI (maralixibat) oral solution and tablets?

LIVMARLI can cause serious side effects, including:

- **Liver injury.** Changes in certain liver tests are common in patients but may worsen during treatment with LIVMARLI. These changes may be a sign of liver injury and can be serious. Your health care provider should do blood tests and physical exams 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
  - your skin or the white part of your eye turns yellow
  - dark or brown urine
  - pain on the right side of your stomach (abdomen)
  - fullness, bloating, or fluid in your stomach area (ascites)
  - loss of appetite
  - bleeding or bruising more easily than normal, including vomiting blood

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## Long-term impact to the liver



Data from 3 long-term clinical studies for LIVMARLI were also assessed to better understand which factors may be linked to living longer without a liver transplant.

### **Patients included in the long-term studies:**

- Had moderate-to-severe cholestatic pruritus (itch)
- Were considered to be benefiting from LIVMARLI
- Stayed on treatment for at least 48 weeks
- Had lab results at 48 weeks



## Transplant-free survival

Transplant free means patients had not undergone a liver transplant. Transplant-free survival refers to **the percentage of patients who are alive and have not gotten a liver transplant** at a certain point in time.



## Long-term impact

Patients who experienced a significant improvement in their cholestatic pruritus were also more likely to experience transplant-free survival.

### **IMPORTANT SAFETY INFORMATION (cont'd)**

#### **What are the possible side effects of LIVMARLI (maralixibat) oral solution and tablets?**

- **Stomach and intestinal (gastrointestinal) problems.** LIVMARLI can cause stomach and intestinal problems, including diarrhea and stomach pain during treatment. Diarrhea can also cause the loss of too much body fluid (severe dehydration). Your health care provider may advise you to monitor for new or worsening stomach problems, including stomach pain, diarrhea, blood in your stool, or vomiting.

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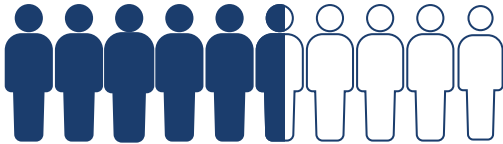
**Patients with >1-point reduction**



**93%** transplant free

For those who achieved more than a 1-point reduction in Itch Reported Outcome (Observer) (ItchRO[Obs]) score, 93% were alive and had not had a transplant 6 years after starting LIVMARLI.\*

**Patients with ≤1-point reduction**



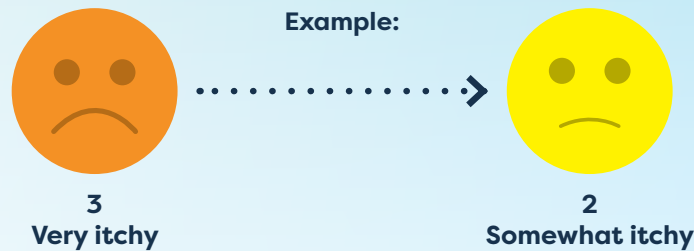
**57%** transplant free

For those who did not achieve more than a 1-point reduction in ItchRO(Obs) score, 57% remained alive and had not had a transplant 6 years after starting LIVMARLI.†

\*The impact of LIVMARLI on transplant-free survival has not been established. No information about liver fibrosis (scarring) was collected.

†During treatment with LIVMARLI, 13 patients had a 1-point or greater reduction in Itch Reported Outcome (ItchRO) score. Five patients did not achieve more than a 1-point reduction in their ItchRO score.

**Changes in ItchRO score of 1 point or more** represent noticeable differences in cholestatic pruritus (itch); for example, a change from 3 to 2 means that a patient went from feeling very itchy to feeling somewhat itchy.



**IMPORTANT SAFETY INFORMATION (cont'd)**

**What are the possible side effects of LIVMARLI (maralixibat) oral solution and tablets?**

- **Stomach and intestinal (gastrointestinal) problems.** Tell your health care provider right away if you have any new or worsening signs or symptoms of stomach and intestinal problems, including:
  - diarrhea
  - severe stomach-area pain or tenderness
  - more frequent bowel movements than usual
  - vomiting
  - stools that are black, tarry, or sticky, or have blood or mucous
  - urinating less often than usual
  - dizziness
  - headache

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## What are the possible side effects?

Side effects can happen as your body is adjusting to LIVMARLI and working to get rid of excess bile. Talk with your doctor about what to expect and how to manage any side effects.

### The most common\* side effects in clinical studies included:

- » Diarrhea (around 6 in 10 people)
- » Abdominal pain (around 5 in 10 people)
- » Vomiting (around 4 in 10 people)
- » Nausea (around 1 in 10 people)
- » Fat-soluble vitamin (FSV) deficiency (around 3 in 10 people)
- » Liver test abnormalities (around 2 in 10 people)
- » Bone fractures (around 1 in 10 people)

#### About gastrointestinal (GI) side effects

- » GI events like diarrhea, abdominal pain, or vomiting may occur as your body adjusts to LIVMARLI. In clinical studies, **most GI side effects were mild to moderate and temporary, lasting less than 1 week**

#### About FSV deficiency

- » Though LIVMARLI may affect absorption of FSVs, **patients with Alagille syndrome can have FSV deficiency at the start of treatment and are often supplemented with FSVs**
- » Because Alagille syndrome can affect vitamin absorption, bone fractures and bleeding may occur

#### About liver test abnormalities

- » High levels of certain liver enzymes called alanine aminotransferase (ALT) and aspartate aminotransferase (AST) can be a sign of liver injury. Your doctor should monitor liver tests during treatment with LIVMARLI

#### Many side effects may improve with proper management

- » Your doctor may adjust your dose, pause treatment briefly, or suggest supportive steps (like diet changes, fluids, or over-the-counter medicines) to ease GI symptoms
- » **Share your concerns.** Whether it's side effects, routine challenges, or cost—your care team can help

\*“Common” defined as occurring in  $\geq 5\%$  of patients treated with LIVMARLI.

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## Two convenient options. One small dose daily.

LIVMARLI is the **ONLY** ileal bile acid transporter (IBAT) inhibitor available as a tablet or a liquid (oral solution) medicine.

Both LIVMARLI tablets and liquid medicine are taken by mouth.

Tablet **or** Liquid

Available in **4** fixed doses



10 mg



15 mg



20 mg

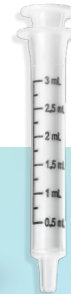


30 mg



Dime shown for scale

Tablets and dime actual size.



3 mL is the largest dose—less than **1 teaspoon**

Bottle and syringe not actual size.

### ONE DOSE, ONCE PER DAY

Both LIVMARLI tablets and liquid medicine should be taken once daily at the dosage prescribed by your doctor. Take LIVMARLI 30 minutes before a meal.

Dosing for LIVMARLI is based on weight.  
**Never change the amount of LIVMARLI without first talking to your doctor.**

#### IMPORTANT SAFETY INFORMATION (cont'd)

##### What are the possible side effects of LIVMARLI (maralixibat) oral solution and tablets?

- A condition called **Fat-Soluble Vitamin (FSV) Deficiency caused by low levels of certain vitamins (vitamin 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, and may monitor for bone fractures and bleeding, which are common side effects.

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# Meet Emma

For Emma, the effects of cholestatic pruritus (itch) were more than skin deep, impacting her not only physically, but socially. Friendships and schooling were challenging to focus on. She felt the itching just became part of everyday life.

*“LIVMARLI helps me manage my itching, and it just lets me go about my daily life without worrying about the itch as much.”*

**Within 2 weeks of starting LIVMARLI, Emma saw improvements in itch. She also experienced:**



Less fidgeting



Fewer sleep disturbances



Less active scratching

Emma did not report any side effects with her LIVMARLI treatment.



**21-year-old real person with Alagille syndrome taking LIVMARLI who is enthusiastic about her art.**  
Individual results may vary.



## IMPORTANT SAFETY INFORMATION (cont'd)

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# Meet Finley

*“When we saw the early signs of itching, like rubbing his eyes and disturbed sleep, our doctor recommended LIVMARLI.”*  
—Dani, Finley’s mom

Finley’s cholestatic pruritus (itch) symptoms often looked like normal newborn behavior. He rubbed against his parents, shuffled his feet, and kicked his legs.

**After starting LIVMARLI, Finley saw itch improvements within 4 weeks. These included improvements in everyday impacts cholestatic pruritus can have:**

Fewer sleep interruptions



More able to focus on his daily routine with fewer distractions



Less overall itching



Finley experienced some gastrointestinal side effects at the start of his LIVMARLI treatment.



**5-year-old real person with Alagille syndrome taking LIVMARLI who likes learning how things work.**  
Individual results may vary.

**Since starting LIVMARLI, both Emma and Finley have found improvements in cholestatic pruritus.**

Visit [LIVMARLI.com](https://www.livmarli.com) to see Emma, Finley, and others share their stories.

## IMPORTANT SAFETY INFORMATION (cont'd)

LIVMARLI is available in oral solution and tablet formulations. LIVMARLI is taken by mouth, 1 time each day, 30 minutes before a meal in the morning. For the oral solution, be sure to use the provided oral dosing dispenser to accurately measure the dose of medicine.

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# Getting started is as easy as L-I-V



**Let your doctor know about any signs or symptoms of cholestatic pruritus (itch).**

If LIVMARLI® (maralixibat) oral solution or tablets is a good fit, your doctor may write a prescription.



**Incoming call:** After your doctor has prescribed LIVMARLI, you'll receive a call from a Patient Navigator at Mirum Access Plus at **1-855-676-4968** who will:

- Assist with insurance coverage
- Discuss support and services Mirum Access Plus can provide—every step of the way



**Victory!** LIVMARLI will be shipped directly to your door.

Your Mirum Access Plus team is there for refills, resources, and support.



**Mirum Access Plus** is a program that will support you by helping you navigate every step of the way. Mirum Access Plus experts will help you:

- **Understand** the process of getting your medication
- **Figure out** insurance coverage and eligibility for financial support programs
- **Connect you** with education and resources that can help you start and stay on LIVMARLI

**Mirum Access Plus works closely with your doctor and insurance plan to help you access LIVMARLI.**

## Do you have questions about Mirum Access Plus?

Visit [LIVMARLI.com](https://www.livmarli.com) or contact us at 1-855-MRM-4YOU (1-855-676-4968). We are available Monday to Friday, from 8:00 AM to 8:00 PM ET.



**[Click here to explore all that Mirum Access Plus has to offer.](#)**

*"It was probably the easiest start  
of a new medication I think I've  
ever been through."*

–Michelle, mom to Téo, living  
with Alagille syndrome



## INDICATION

LIVMARLI (maralixibat) oral solution and tablets are a prescription medicine used to treat cholestatic pruritus (itch) in patients who are 3 months of age and older with Alagille syndrome.

It is not known if LIVMARLI is safe and effective in children with Alagille syndrome who are under 3 months of age. It is not known if LIVMARLI is safe and effective in adults who are 65 years of age and older.

## IMPORTANT SAFETY INFORMATION

### What are the possible side effects of LIVMARLI (maralixibat) oral solution and tablets?

LIVMARLI can cause serious side effects, including:

- **Liver injury.** Changes in certain liver tests are common in patients but may worsen during treatment with LIVMARLI. These changes may be a sign of liver injury and can be serious. Your health care provider should do blood tests and physical exams 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
  - your skin or the white part of your eye turns yellow
  - dark or brown urine
  - pain on the right side of your stomach (abdomen)
  - fullness, bloating, or fluid in your stomach area (ascites)
  - loss of appetite
  - bleeding or bruising more easily than normal, including vomiting blood
- **Stomach and intestinal (gastrointestinal) problems.** LIVMARLI can cause stomach and intestinal problems, including diarrhea and stomach pain during treatment. Diarrhea can also cause the loss of too much body fluid (severe dehydration). Your health care provider may advise you to monitor for new or worsening stomach problems, including stomach pain, diarrhea, blood in your stool, or vomiting. Tell your health care provider right away if you have any new or worsening signs or symptoms of stomach and intestinal problems, including:
  - diarrhea
  - more frequent bowel movements than usual
  - stools that are black, tarry, or sticky, or have blood or mucous
  - severe stomach-area pain or tenderness
  - vomiting
  - urinating less often than usual
  - dizziness
  - headache
- A condition called **Fat-Soluble Vitamin (FSV) Deficiency caused by low levels of certain vitamins (vitamin 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, and may monitor for bone fractures and bleeding, which are common side effects.

**Please see additional Important Safety Information for LIVMARLI throughout and full Prescribing Information, including Patient Information and Instructions for Use.**



When cholestatic pruritus (itch) relief takes root with LIVMARLI

# Imagine what may Flourish

## Early improvements with long-term impact\*

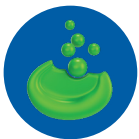
LIVMARLI is the **ONLY** IBAT medicine with all of the following:



**7 years of data** in patients with Alagille syndrome



**Growth (height and weight) data** in patients with Alagille syndrome over 7 years<sup>†</sup>



**Bilirubin data** in patients with Alagille syndrome showing lower levels over 7 years



**Data linking cholestatic pruritus relief to living longer without a liver transplant** in patients with Alagille syndrome<sup>‡</sup>



**Liquid (oral solution) medicine or tablet options**



**1500+ patients have used LIVMARLI** to treat their cholestatic pruritus in the last 7+ years<sup>§</sup>



**Getting started and finding support is easy**

Mirum Access Plus works closely with your doctor and insurance plan to help you access LIVMARLI.

Discover **resources, education, and services** for every part of your journey.

Explore more at [LIVMARLI.com](https://LIVMARLI.com)

IBAT=ileal bile acid transporter.

\*Based on data from MERGE, which evaluated results from 3 clinical studies to determine how long-term treatment affected cholestatic pruritus. These included data from 86 patients, including 23 who stayed on treatment for 7 years.

<sup>†</sup>A total of 23 patients were evaluated for cholestatic pruritus improvements at 7 years.

<sup>‡</sup>From extended observation of patients taking LIVMARLI after completing a placebo-controlled study. The impact of LIVMARLI medicine on transplant-free survival has not been established. No information about liver fibrosis (scarring) was collected.

<sup>§</sup>Includes clinical studies, early access program, and commercial treatment. Not all patients taking LIVMARLI will have the same experiences.

### IMPORTANT SAFETY INFORMATION (cont'd)

These are not all of the possible side effects of LIVMARLI. For more information, ask your health care provider or pharmacist. Call your doctor for medical advice about side effects. You may report side effects to the FDA at 1-800-FDA-1088.

Please see additional Important Safety Information for LIVMARLI throughout and full Prescribing Information, including Patient Information and Instructions for Use.



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