

Rise above cholestatic pruritus (itch) to

LIV IT UP

EMMA
20 years old
Real person taking LIVMARLI



ABBY
26 years old
Real person taking LIVMARLI



LIVMARLI is an **FDA-approved medicine** for cholestatic pruritus in patients with Alagille syndrome who are 3 months of age and older.

IMPORTANT SAFETY INFORMATION

What are the possible side effects of LIVMARLI?

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.

Please see page 2 for more information on liver tests.



Please see Important Safety Information throughout and full [Patient Information](#).

 **Livmarli**[®]
(maralixibat) oral solution

A Medicine for Cholestatic Pruritus (Itch)
in Alagille Syndrome

DISCOVER LIVMARLI

Finding out that you have Alagille syndrome can be hard.
Finding ways to manage the condition can be even harder.

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



EMMA



ABBY

.....

Explore Alagille syndrome stories.

Check out pages 14 and 15 to meet Emma and Abby: 2 adults who take LIVMARLI to help treat cholestatic pruritus in Alagille syndrome.

.....



IMPORTANT SAFETY INFORMATION (cont'd)

What are the possible side effects of 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



Please see Important Safety Information throughout and full [Patient Information](#).

WHAT CAN YOU FIND IN THIS INFORMATIONAL GUIDE?

4	The liver and cholestatic pruritus (itch)
6	Impact of cholestatic pruritus
7	Cholestatic pruritus and normalization
8	How does LIVMARLI work to reduce cholestatic pruritus in the body?
9	Early cholestatic pruritus improvements
10	Long-term impact to the liver
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14	Meet others with Alagille syndrome: Emma
15	Meet others with Alagille syndrome: Abby
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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 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



Please see Important Safety Information throughout and full [Patient Information](#).

THE LIVER AND CHOLESTATIC PRURITUS (ITCH)

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

1

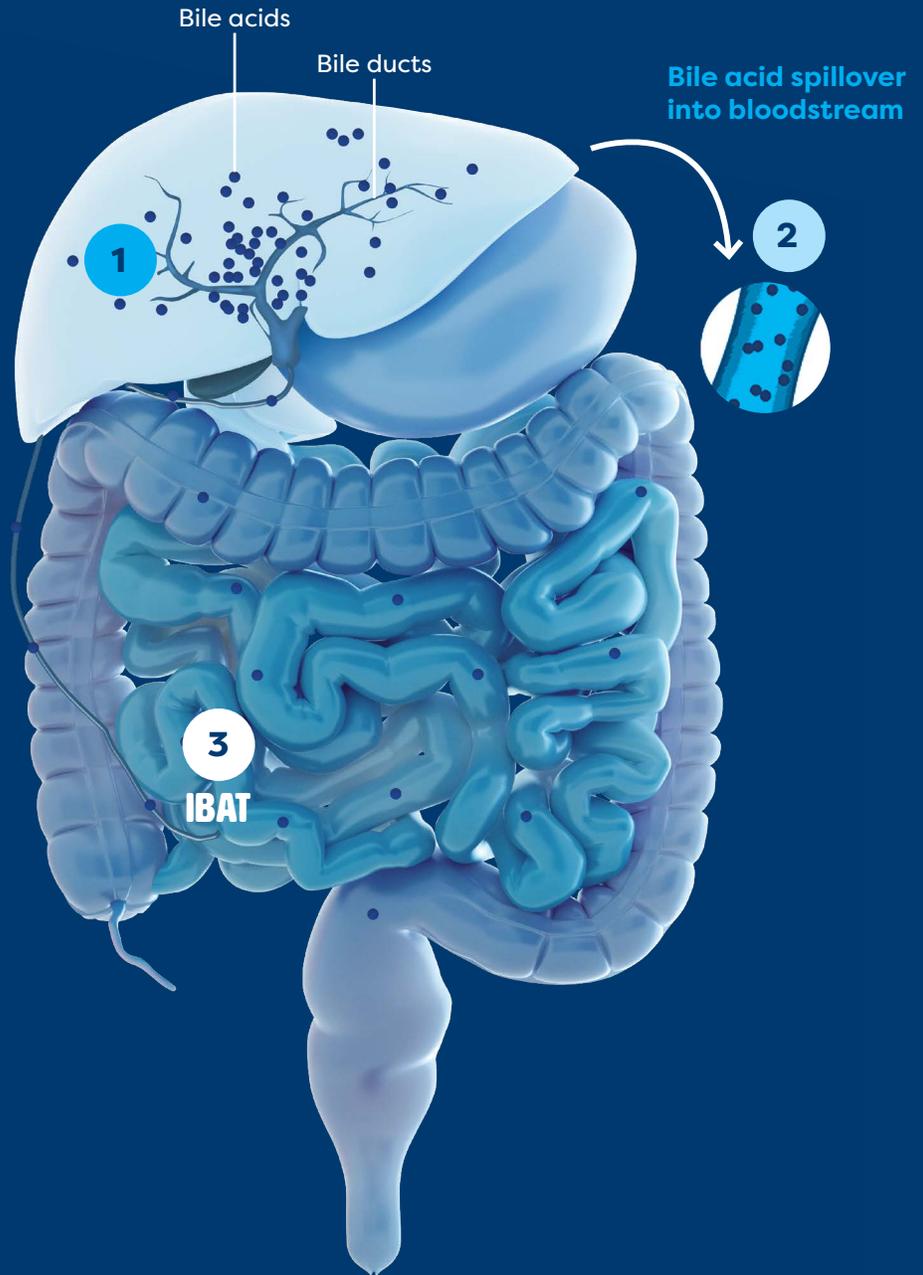
People with Alagille syndrome have too few bile ducts, which prevents bile from flowing out of the liver.

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).

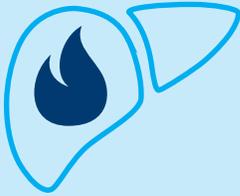


THE LIVER AND CHOLESTATIC PRURITUS (ITCH)

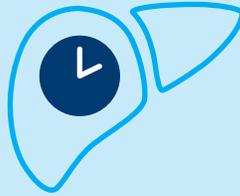
Bile acid buildup may cause immediate problems (cholestatic pruritus) and have long-term impacts (liver problems).

Over time, the buildup of bile acids in the liver can lead to:

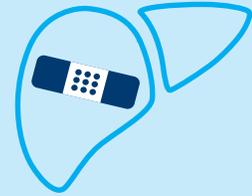
Inflammation



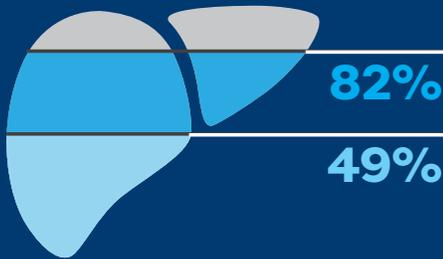
Damage to the liver that worsens over time



Scar tissue in the liver (fibrosis)



The need for effective treatment



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.

In Alagille syndrome, persistent cholestatic pruritus was a reason for **49% to 82%** of liver transplants.

Read on to uncover the real impact of cholestatic pruritus, including commonly overlooked symptoms and information about normalization.



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 all aspects of cholestatic pruritus without the right support. Signs and symptoms related to cholestatic pruritus can look different during the day and/or night, vary among patients, or even change with age.

The burden of cholestatic pruritus

zZz

53%
have trouble
falling asleep

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 prickling
sensation



Irritability



Rubbing of
the feet



Skin
damage



Physical
discomfort



Inability
to focus



CHOLESTATIC PRURITUS (ITCH) AND NORMALIZATION



Cholestatic pruritus 101: Did you know?

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 year. Some people refer to **times when cholestatic pruritus is worse as a “flare-up.”**

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

All levels of cholestatic pruritus deserve attention.

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

Check out [LIVMARLI.com/between-the-fines/](https://www.livmarli.com/between-the-fines/) to hear real people open up about their lives with cholestatic pruritus.



HOW DOES LIVMARLI WORK TO REDUCE CHOLESTATIC PRURITUS 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).

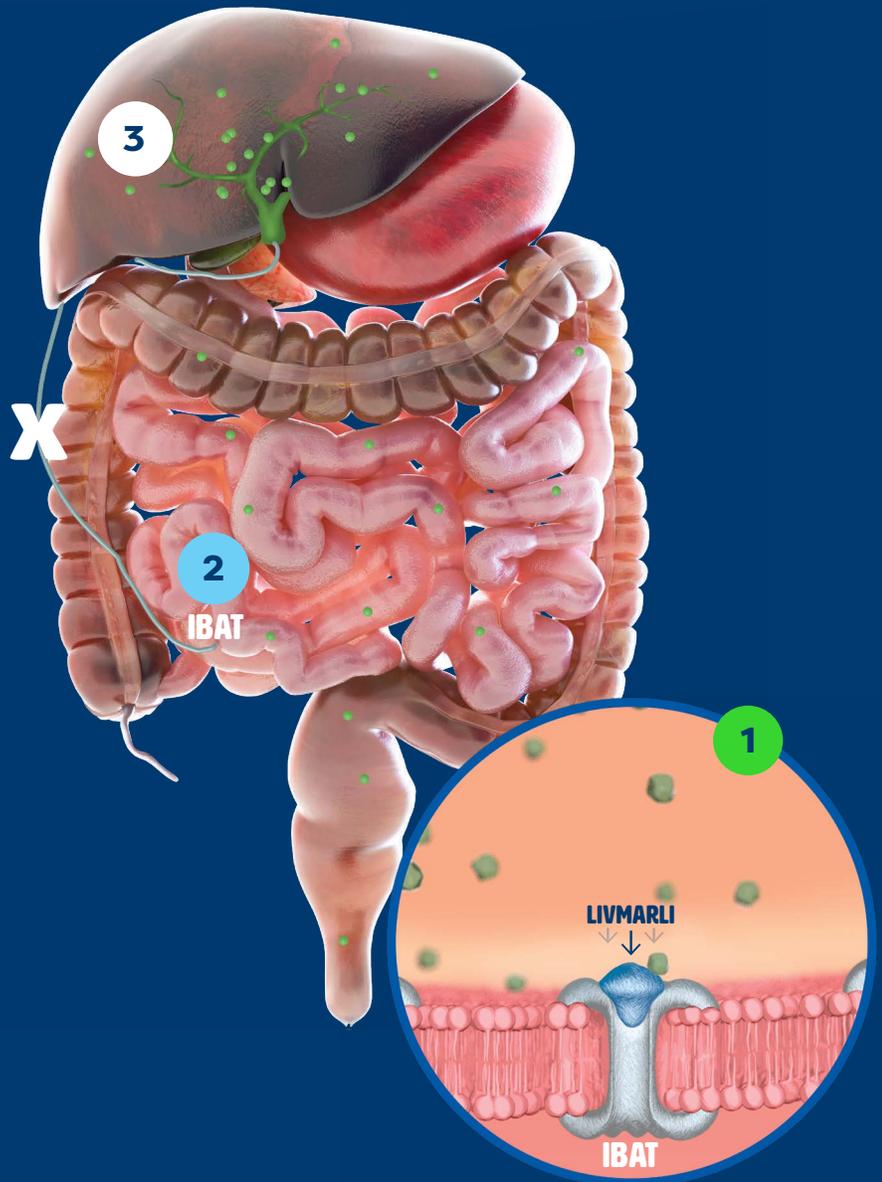
2

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?

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



Please see Important Safety Information throughout and full [Patient Information](#).

Rapid Relief That Lasts

EARLY CHOLESTATIC PRURITUS (ITCH) IMPROVEMENTS

The goal of LIVMARLI is to provide **fast and lasting relief from cholestatic pruritus.**

Patients were treated with LIVMARLI in a 4-year clinical study. During that time, **many patients taking LIVMARLI experienced significantly less cholestatic pruritus.**



Early Improvements

For many patients taking LIVMARLI, relief from cholestatic pruritus was seen **at the very first assessment** (Week 3) and continued through the first year.



Relief With LIVMARLI

During the first year of treatment with once-daily LIVMARLI, **more than 80% of patients experienced less cholestatic pruritus** than they felt at the start of treatment.



Lasting Results

For those who stayed on LIVMARLI in the long-term part of the study, **relief from cholestatic pruritus was maintained for nearly 4 years.**

During the long-term study, patients experienced **little to no cholestatic pruritus** for the vast majority (95%) of days.

Over the last 6+ years, LIVMARLI has been used by **850+ patients** to battle bile acid buildup.*

*Includes clinical studies, early access program, and commercial treatment.

Once-daily LIVMARLI offers meaningful, long-lasting improvements in cholestatic pruritus for patients with Alagille syndrome.

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 (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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 **Livmarli**[®]
(maralixibat) oral solution

LONG-TERM IMPACT TO THE LIVER

There were **3 clinical studies** conducted for patients with **Alagille syndrome**. Some patients from the clinical studies chose to **stay on LIVMARLI long term**. These patients were observed to see if there were any factors that could predict transplant-free survival.



Patients kept a log of their cholestatic pruritus using the **Itch Reported Outcome (ItchRO) tool**, which measures **cholestatic pruritus severity over time based on a 5-point scale**. They were assessed to determine the relationship between their cholestatic pruritus intensity score and transplant-free survival.

Patients included in the long-term studies:

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



Transplant Free

Transplant free means patients were alive and 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 cholestatic pruritus** were also more likely to **experience transplant-free survival**.

IMPORTANT SAFETY INFORMATION (cont'd)

What are the possible side effects of LIVMARLI?

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



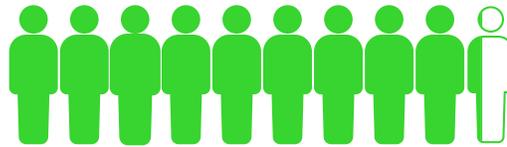
Please see Important Safety Information throughout and full [Patient Information](#).

LONG-TERM IMPACT TO THE LIVER

Persistent cholestatic pruritus was a common reason for liver transplant in many patients with Alagille syndrome.

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

Patients with >1 point reduction



93%
TRANSPLANT FREE

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

Patients with ≤1 point reduction



57%
TRANSPLANT FREE

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

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



3

Very itchy



2

Somewhat itchy

IMPORTANT SAFETY INFORMATION (cont'd)

What are the possible side effects of LIVMARLI?

- **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
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 - 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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Once-Daily Medicine

HOW IS LIVMARLI TAKEN?

ONE DOSE, ONCE PER DAY

Once you and your doctor have decided that once-daily LIVMARLI is the right treatment, here's how and when you can take your liquid medicine:



How is LIVMARLI taken?

LIVMARLI is a **liquid medicine taken by mouth** directly from a measuring device that's delivered with your medicine.



When is LIVMARLI taken?

LIVMARLI is taken **1 time each day**, 30 minutes before a meal in the morning.



How much LIVMARLI is taken?

Your doctor will prescribe the right dose for you.

Most adult patients will take 3 mL or less—just a little more than half a teaspoon.

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?

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, colestipol, or colestipol, take it at least 4 hours before or 4 hours after you take LIVMARLI.



Please see Important Safety Information throughout and full [Patient Information](#).

HOW IS LIVMARLI TAKEN?

What else do I need to know about taking LIVMARLI?

Taking LIVMARLI every day exactly as your doctor tells you to is the **best way to see improvements** in cholestatic pruritus (itch) in Alagille syndrome. Of course, balancing dosing with work, school, and/or social activities isn't always easy, but making it a priority every day will help to maintain cholestatic pruritus relief.

What happens if a dose is missed?

- If you miss a dose within 12 hours of the time you normally take it, take LIVMARLI as soon as possible
- If a dose is missed by more than 12 hours, skip the dose and continue your original dosing schedule the next day

What are the possible side effects of LIVMARLI?

LIVMARLI may cause side effects. Talk to your doctor about what to expect and how to manage any side effects.

The most common side effects with LIVMARLI include:

- Diarrhea
- Abdominal pain
- Vomiting
- 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
- Other common side effects reported during treatment with LIVMARLI were liver test abnormalities and bone fractures

Your doctor may change your dose or temporarily or permanently stop treatment with LIVMARLI if you have certain side effects. These are not all the possible side effects of LIVMARLI. Call your doctor for medical advice about side effects. You may report side effects to the FDA at 1-800-FDA-1088.



Please see Important Safety Information throughout and full [Patient Information](#).

MEET EMMA



20 Years Old
Real person taking LIVMARLI

Individual results may vary

Emma was diagnosed with Alagille syndrome by the time she was 3 months old. Her cholestatic pruritus (itch) resulted in constant active scratching, leading to red marks, bleeding, and scarring.

Cholestatic pruritus made Emma moody and irritable and caused significant sleep disturbances. Emma's mom said she would often rip holes in her clothing and bite at her skin.

“The itching just became my everyday life. No matter how severe it was or how bad it was, that was just my life. I just lived with it. Looking back, that was not normal.”

—Emma

IMPORTANT SAFETY INFORMATION (cont'd)

What are the possible side effects of LIVMARLI?

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

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



Please see Important Safety Information throughout and full [Patient Information](#).

MEET ABBY



26 Years Old
Real person taking LIVMARLI

Individual results may vary

Abby was diagnosed with Alagille syndrome by the time she was 11 months old. She had constant active scratching “from the time that I was able to start to itch,” she says. Abby underwent a biliary diversion by the age of 2.

Cholestatic pruritus (itch) caused significant sleep disturbances, which left her feeling tired and groggy at work.

“Looking back, the pruritus has always been normalized for me. It was just something I had to live with.”

–Abby



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

Watch Emma and Abby share their perspectives on growing up with cholestatic pruritus and finally starting to find relief with LIVMARLI.

Visit [LIVMARLI.com](https://www.livmarli.com) to check out their full conversation.

IMPORTANT SAFETY INFORMATION (cont'd)

What are the possible side effects of LIVMARLI?

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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Getting Started Is Easy

Mirum Access Plus



Approximately **94%** of patients are approved for LIVMARLI by their insurance and **98%** of patients pay **\$10 or less per fill**.^{*†}

Mirum Access Plus is a support program that makes it easy for you to start and stay on LIVMARLI.

Once your doctor has sent your prescription to Mirum Access Plus, the dedicated team of experts will help you understand the process of getting your medication.

Within Your Reach



Insurance coverage assistance

Mirum Access Plus experts will work with you and your health care team to **figure out insurance coverage**.



Refill reminders and support

Mirum Access Plus experts will contact you with **refill reminders** and assist you with any steps needed before shipping the refill.



Coordinated delivery

Mirum Access Plus experts will **conveniently ship your medication straight to your doorstep overnight** when coverage is approved.

There's More to Mirum Access Plus

When you sign up, Mirum Access Plus offers an enhanced, personalized experience that's designed to help you start and stay on therapy with education and resources—**at no cost to you.**



You can sign up by texting MIRUM to 47936 or calling us at 1-855-MRM-4YOU (1-855-676-4968)

Do you have questions about Mirum Access Plus?

Visit LIVMARLI.com/mirum-access-plus-map/ 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.

^{*}Data from 1/1/2022 to 12/31/2023.

[†]Patients enrolled in the Mirum Patient Assistance Program are included in those paying \$10 or less per fill.



Please see Important Safety Information throughout and full [Patient Information](#).

INDICATION

LIVMARLI is 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

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 - 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.

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 it at least 4 hours before or 4 hours after you take LIVMARLI.

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

LIVMARLI is taken by mouth, 1 time each day, 30 minutes before a meal in the morning. 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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Rise above cholestatic pruritus (itch) to

LIV IT UP



EARLY IMPROVEMENTS WITH LONG-TERM IMPACT

More than 80% of patients experienced less cholestatic pruritus than they felt at the start with LIVMARLI. Improvements were seen as early as the very first assessment (Week 3). For patients who experienced a significant improvement in cholestatic pruritus—that is, more than a 1-point reduction in Itch Reported Outcome (Observer) (ItchRO[Obs])*—93% were alive and did not have a liver transplant 6 years after starting LIVMARLI (please see important study design information on pages 10 and 11).^{†‡}

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

[‡]Persistent cholestatic pruritus was a common reason for liver transplant in many patients with Alagille syndrome.



HELPING PATIENTS FOR YEARS

Backed by more than 5 years of data,[§] LIVMARLI has a well-known safety record in patients with cholestatic pruritus in Alagille syndrome.

Over the last 6+ years, LIVMARLI has been used by 850+ patients with Alagille syndrome to battle bile acid buildup.^{||}

^{||}Includes clinical studies, early access program, and commercial treatment.



GETTING STARTED AND FINDING SUPPORT IS EASY

Approximately 94% of patients are approved for LIVMARLI by their insurance and 98% of patients pay \$10 or less per fill.^{†#} Mirum Access Plus offers resources, education, and services to help you start and stay on LIVMARLI.

To learn more about LIVMARLI, talk to your doctor or visit LIVMARLI.com

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LIVMARLI is 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.

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*ItchRO(Obs) is a tool designed for caregivers to measure cholestatic pruritus severity over time.

[§]From extended observation of patients taking LIVMARLI after completing a placebo-controlled study.

[†]Data from 1/1/2022 to 12/31/2023.

[#]Patients enrolled in the Mirum Patient Assistance Program are included in those paying \$10 or less per fill.



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