

Rise above cholestatic
pruritus (itch) to

LIV IT UP

TYLER
20 years old
Real person taking LIVMARLI



CHARMAINE
16 years old
Real person taking LIVMARLI



CJ
14 years old
Real person taking LIVMARLI



LIVMARLI (maralixibat) oral solution and tablets are an **FDA-approved prescription medicine** used to treat cholestatic pruritus (itch) in patients 12 months of age and older with progressive familial intrahepatic cholestasis (PFIC).

LIVMARLI is not for use in PFIC type 2 patients who have a severe defect in the bile salt export pump (BSEP) protein.

It is not known if LIVMARLI is safe and effective in children with PFIC who are under 12 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 with PFIC but may worsen during treatment.

Please see page 2 for more information on liver injury.



Please see Important Safety Information throughout and
Patient Information, including Instructions for Use.

 **Livmarli**[®]
(maralixibat)

A Medicine for Cholestatic Pruritus (Itch) in PFIC

DISCOVER LIVMARLI

Living with progressive familial intrahepatic cholestasis (PFIC) can be challenging.
Finding ways to manage the condition can be even harder.

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



TYLER



CHARMAINE



CJ

.....

Explore real patient stories.

Check out pages 14 to 15 to meet
Tyler, Charmaine, and CJ: 3 people
who take LIVMARLI to help treat
cholestatic pruritus in PFIC.

.....



IMPORTANT SAFETY INFORMATION (cont'd)

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

These changes may be a sign of liver injury and can be serious or may lead to liver transplant or death. Your health care provider should do blood tests and physical exams before starting and during treatment with LIVMARLI 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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throughout and Patient Information,
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 **Livmarli**[®]
(maralixibat)

WHAT CAN YOU FIND IN THIS INFORMATIONAL GUIDE?

4	How does PFIC affect the liver and cause cholestatic pruritus (itch)?
6	Impact of cholestatic pruritus (itch)
8	LIVMARLI for cholestatic pruritus (itch) in PFIC
9	How does LIVMARLI work to reduce cholestatic pruritus (itch) in the body?
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14	Meet others with PFIC: Tyler, Charmaine, and CJ
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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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WHAT IS PFIC?

Progressive familial intrahepatic cholestasis (PFIC) is a group of rare, inherited diseases that mostly affects the liver.

There are 3 main types of PFIC and several other, rarer types. These are called subtypes. The 2 most common subtypes are PFIC2 and PFIC3.

Here are the 3 main types of PFIC:

PFIC1

This type of PFIC is defined by **changes to a protein in the liver called familial intrahepatic cholestasis associated protein 1 (FIC1)**. PFIC1 is not very common

PFIC2

This is the most common type. It is caused by **changes to a protein in the liver called the bile salt export pump (BSEP)**, and makes up **approximately half** of all cases

PFIC3

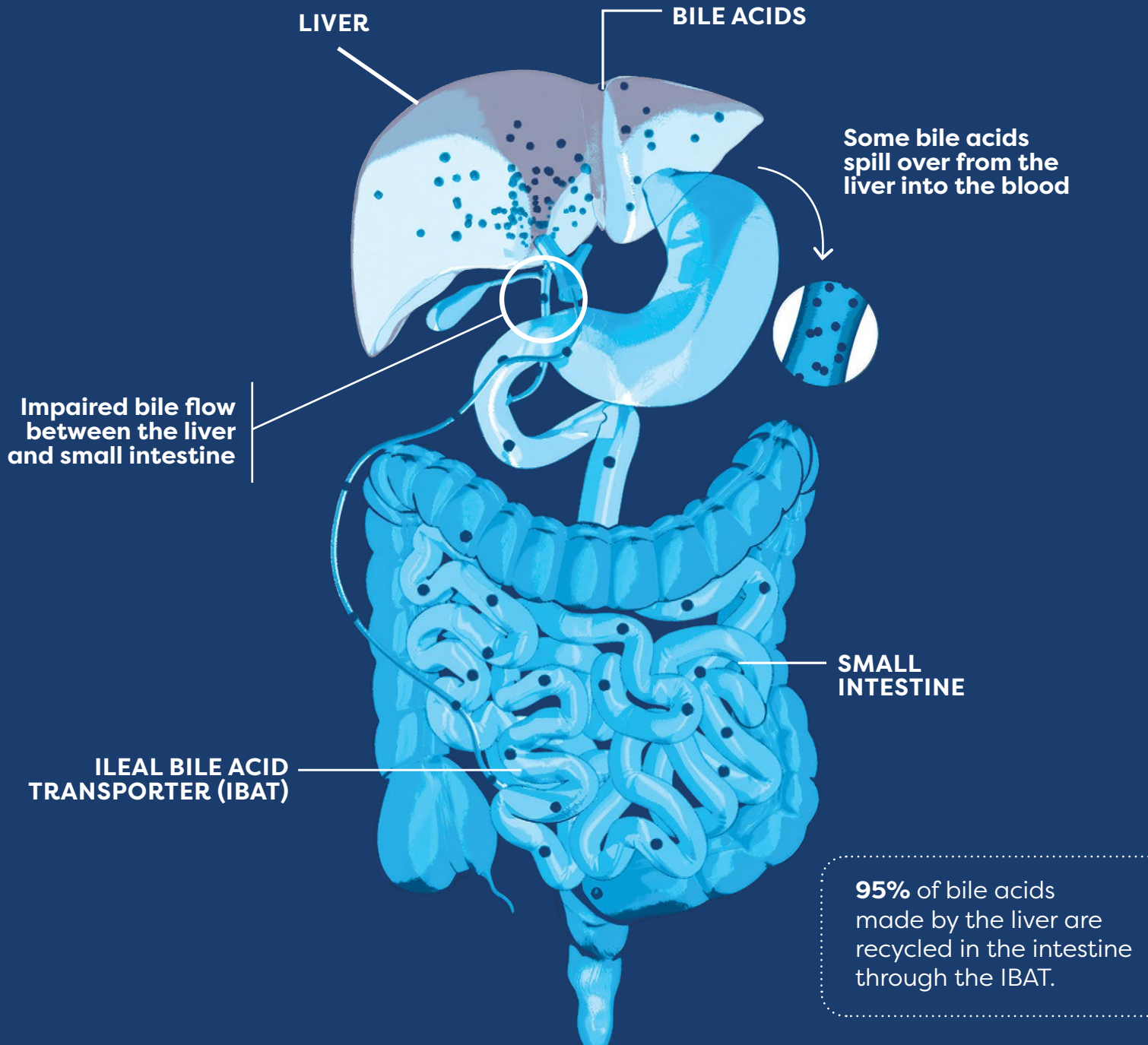
Making up **approximately one-third of all cases**, PFIC3 results from **changes to a protein in the liver called multidrug resistance class III (MDR3)**

WHAT IS PFIC?

How does progressive familial intrahepatic cholestasis (PFIC) affect the liver?

The liver makes a fluid called bile that helps with the digestion of fats. Bile acids, which are a part of bile, are made by the liver cells. In PFIC, bile acids get stuck inside the cells.

Over time, bile acids build up in the liver and blood.



WHAT ARE THE EFFECTS OF BILE ACID BUILDUP?

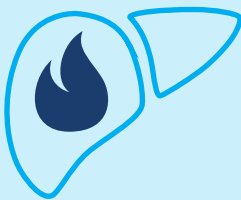
When bile acids build up in the liver, they spill over into the bloodstream.
This can cause an increase in bile acids throughout the entire body.

These **high levels of bile acids are an underlying cause of cholestatic pruritus (itch)** in progressive familial intrahepatic cholestasis (PFIC).

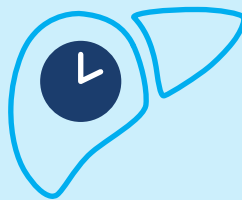
Cholestatic pruritus affects
76% to 100%
of people with PFIC and is also the
most burdensome symptom

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

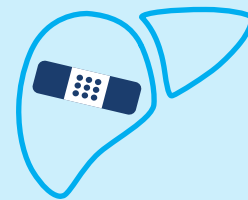
Inflammation



Damage to the liver
that worsens over time



Scar tissue in
the liver (fibrosis)



The need for effective treatment

Treatment options for cholestatic pruritus in PFIC have been limited.

Medication that helps normalize the flow of bile acids to reduce cholestatic pruritus fills a crucial role in disease management.

IMPACT OF CHOLESTATIC PRURITUS (ITCH)

Cholestatic pruritus is often a very challenging symptom for people with progressive familial intrahepatic cholestasis (PFIC).

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.



Sleep disturbances



Worsened physical function



Skin damage



Worsened general health



Irritability



Cognitive impact (information processing, poor attention)



Potential negative impact on social activities



Burning, tingling, or prickling sensation

An FDA-Approved Treatment

LIVMARLI FOR CHOLESTATIC PRURITUS IN PFIC

LIVMARLI is an FDA-approved treatment for cholestatic pruritus (itch) in patients with progressive familial intrahepatic cholestasis (PFIC) who are 12 months of age and older. LIVMARLI helps lower bile acid buildup and relieve cholestatic pruritus.



The Broadest Population of PFIC Subtypes Studied*

LIVMARLI has **proven results across 5 PFIC subtypes**.

LIVMARLI has a **well-known safety profile** in patients with cholestatic pruritus in PFIC.

*LIVMARLI is not for use in patients with PFIC type 2 who have a severe defect in the bile salt export pump (BSEP) protein.



Early and Lasting Improvements in Cholestatic Pruritus

Improvements in cholestatic pruritus were seen **as early as 2 weeks** after starting LIVMARLI and **continued through 2 years**.

64% of patients experienced meaningful improvements in cholestatic pruritus within the first 6 months of treatment with LIVMARLI.



Getting Started Is Easy

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Get started by texting MIRUM to 47936, or call 1-855-MRM-4YOU (1-855-676-4968) Monday through Friday, 8:00 AM through 8:00 PM ET.

IMPORTANT SAFETY INFORMATION (cont'd)

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

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



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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).

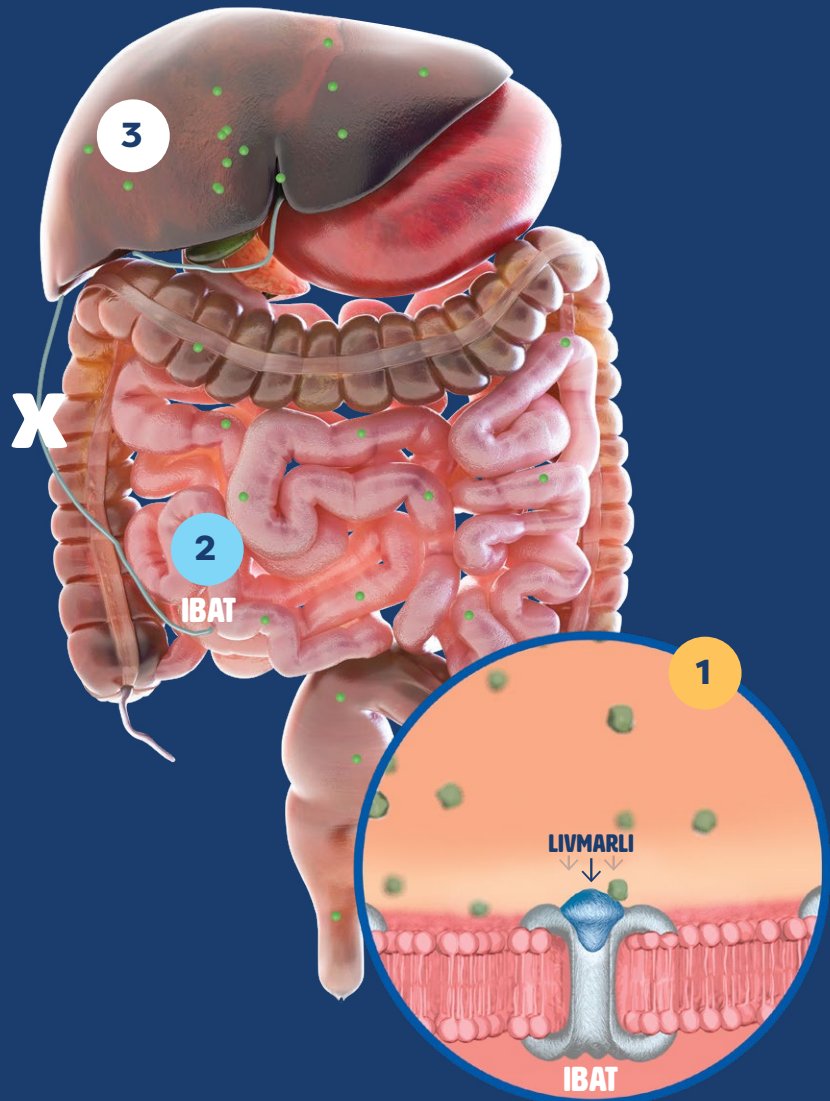
2

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, patients had reductions in cholestatic pruritus and bile acid buildup.

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?

- 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 PFIC 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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MORE RELIEF WITH LIVMARLI

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

How Cholestatic Pruritus Was Assessed

In a 6-month clinical study, patients with progressive familial intrahepatic cholestasis (PFIC) were treated with either LIVMARLI or placebo* to see if LIVMARLI reduced bile acid buildup and improved cholestatic pruritus.

Patients in the study were split into multiple cohorts, or groups:

PFIC2 Group

Only included patients with PFIC2

All-PFIC Group

Included patients with PFIC2 as well as patients with PFIC1, PFIC3, PFIC4, or PFIC6

Other patients with less common or more variable forms of PFIC were also studied.

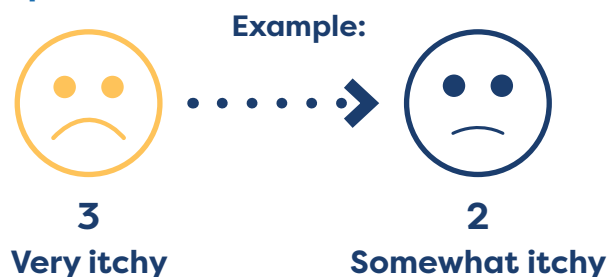
Patients also had the option to continue taking LIVMARLI for up to 2 years as part of a long-term study.

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

The ItchRO tool

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

Changes in ItchRO score by 1 point or more represent noticeable differences in cholestatic pruritus and doctors see them as **“clinically meaningful.”**



IMPORTANT SAFETY INFORMATION (cont'd)

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

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, colestevlam, or colestipol, take LIVMARLI at least 4 hours before or 4 hours after you take that medicine.



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Rapid Relief That Lasts

EARLY IMPROVEMENTS IN CHOLESTATIC PRURITUS (ITCH)

Improvements in cholestatic pruritus were seen as early as 2 weeks and continued throughout treatment with LIVMARLI in both the PFIC2 group and the All-PFIC group.

PFIC2 Group

During the first 6 months of treatment, patients taking LIVMARLI in the PFIC2 group saw **significant improvements in cholestatic pruritus** compared with those who took placebo.

All-PFIC Group



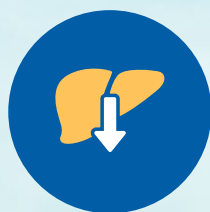
64% SAW IMPROVEMENTS IN CHOLESTATIC PRURITUS

During the 6 months of treatment with LIVMARLI, **64% of those in the All-PFIC group experienced noticeable improvements in cholestatic pruritus**, vs 29% of those receiving placebo.



62% HAD LITTLE OR NO CHOLESTATIC PRURITUS

In the first 6 months of treatment, **62% of patients treated with LIVMARLI had significantly more days with little or no cholestatic pruritus** (had an ItchRO score of 0 or 1) compared with 28% of patients who received placebo.



50% SAW IMPROVEMENTS IN SBA LEVELS

Those taking LIVMARLI in the All-PFIC group also saw **significantly greater improvements in serum bile acid (sBA) levels** than those who took placebo.

50% of patients taking LIVMARLI had their sBA levels reduced by more than 75% or had their sBA decrease to below 102 $\mu\text{mol/L}$, compared with 7% of patients taking placebo.



Lasting Results

Those who stayed on LIVMARLI in the long-term study felt **relief from cholestatic pruritus through 2 years**.

IMPORTANT SAFETY INFORMATION (cont'd)

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

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



Please see Important Safety Information throughout and Patient Information, including Instructions for Use.

One Dose, Twice per Day

HOW IS LIVMARLI TAKEN?

LIVMARLI is the only IBAT inhibitor available as a tablet or a liquid (oral solution) medicine. Both LIVMARLI tablets and liquid medicine are taken by mouth.

LIVMARLI liquid medicine

Take directly from the measuring device delivered with your medicine.



LIVMARLI bottle and measuring device not actual size.

LIVMARLI tablets

Tablets come in 4 fixed doses:



Tablets and dime not actual size. Dime shown for scale.

ONE DOSE, TWICE PER DAY

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

Dosing information:

- Your doctor will prescribe the right dose of LIVMARLI for you
- Dosing for LIVMARLI is based on weight. **Never change the amount of LIVMARLI without first talking to your doctor**
- People who take LIVMARLI liquid medicine will take 2 mL or less per day—**about half a teaspoon**

Why is it important to take LIVMARLI every day?

It can be hard to juggle taking your medicine with work, school, and/or social activities, but **staying on therapy**—even after you start feeling relief from cholestatic pruritus (itch)—**can help prevent breakthrough cholestatic pruritus (itch).**

What happens if a dose is missed?

If you miss a dose within 6 hours of the time you normally take it, take LIVMARLI as soon as possible. **If a dose is missed by more than 6 hours**, skip the dose and continue your original dosing schedule throughout the day.

IMPORTANT SAFETY INFORMATION (cont'd)

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

LIVMARLI is available in oral solution and tablet formulations. Take LIVMARLI exactly as your health care provider tells you to and do not change your dose unless you are instructed to. In patients with PFIC, LIVMARLI is taken by mouth, 2 times each day, 30 minutes before a meal. For the oral solution, be sure to use the provided oral dosing dispenser to accurately measure the dose of medicine.



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WHAT ARE THE POSSIBLE SIDE EFFECTS OF LIVMARLI?

Side effects can happen as your body is adjusting to LIVMARLI and working to get rid of excess bile. In the clinical study, these were most common*:

Diarrhea was reported in around 6 in 10 people, and **stomach pain** in around 3 in 10 people

Liver test abnormalities were seen in around 2 in 10 people

Rectal bleeding was seen in around 1 in 10 people

Bone fractures were reported in around 1 in 10 people



In most cases, diarrhea and stomach pain were mild and temporary, lasting 5.5 days, on average

Fat-soluble vitamin (FSV) deficiency is common in patients with progressive familial intrahepatic cholestasis (PFIC). LIVMARLI may affect absorption of FSV; however, in the clinical study, **FSV deficiency occurred more often in the placebo group (around 4 in 10) than in the LIVMARLI group (around 3 in 10).**



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

IMPORTANT SAFETY INFORMATION (cont'd)

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

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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MEET TYLER



20 Years Old

Taking LIVMARLI since 2014

Individual results may vary.

“After starting LIVMARLI, I wasn’t waking up as much at night to scratch and I felt less need to stop to itch when playing outside with my friends.”

—Tyler

Tyler was diagnosed with progressive familial intrahepatic cholestasis (PFIC) at 6 months old. His cholestatic pruritus (itch) resulted in constant active scratching, making Tyler fussy and irritable. His cholestatic pruritus also caused significant sleep disturbances and negatively impacted social activities.

Since starting LIVMARLI at 10 years old, Tyler has been scratching less, feels less irritable, has fewer sleep disturbances, and can better enjoy socializing with his friends.

MEET CHARMAINE



16 Years Old

Taking LIVMARLI since 2014

Individual results may vary.

“I’m thankful that I’ve had access to LIVMARLI to treat my cholestatic pruritus in PFIC. I can honestly say that LIVMARLI has really improved my cholestatic pruritus.”

—Charmaine

Charmaine was diagnosed with PFIC at just 8 weeks old. Through the years, living with cholestatic pruritus was challenging for Charmaine. It resulted in skin damage, significant sleep disturbances, and constant fidgeting. Her cholestatic pruritus also made it difficult for Charmaine to focus in school.

Since starting LIVMARLI, Charmaine has experienced significantly less scratching, has fewer scratch marks and scabs, has fewer sleep disturbances, and can better focus in school.

IMPORTANT SAFETY INFORMATION (cont’d)

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LIVMARLI can cause serious side effects, including:

- **Liver injury.** Changes in certain liver tests are common in patients with PFIC but may worsen during treatment. These changes may be a sign of liver injury and can be serious or may lead to liver transplant or death.



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MEET CJ



"Thanks to LIVMARLI, I no longer itch like I did when I was younger. I'm thankful it's worked for me."

—CJ

14 Years Old

Taking LIVMARLI since 2015

Individual results may vary.

CJ was diagnosed with progressive familial intrahepatic cholestasis (PFIC) at just 8 months old. Managing his cholestatic pruritus (itch) was a constant challenge for his family, who used socks on his hands and onesies to help prevent scratching, especially at night.

Since starting LIVMARLI, CJ has been able to spend less time scratching and more time focusing on friends and school.



pfic

Advocacy & Resource Network, Inc.

Get to know others like Tyler, Charmaine, and CJ.

PFIC Network is a nonprofit organization that strives to improve the lives of patients and families affected by PFIC worldwide. They value and provide connection, education, and support to the PFIC community. You're not alone in this journey.

Visit the PFIC Network at pfic.org

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- dark or brown urine
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- loss of appetite
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 **Livmarli**[®]
(maralixibat)

Getting Started Is Easy

Mirum Access Plus



Eligible patients may pay as little as **\$10 out of pocket per fill** for LIVMARLI*

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](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.

*Eligibility restrictions: The Mirum Access Plus Savings Program is not available to individuals who use any state or federal government-funded health care program to cover a portion of medication costs, such as Medicare, Medicaid, TRICARE, Department of Defense, or Veterans Administration, or any other state or federal government-funded health care program.



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INDICATION

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THE BROADEST POPULATION OF PFIC SUBTYPES STUDIED*

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