

In patients with cholestatic pruritus (itch)
in Alagille syndrome...

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

FINDINGS FROM A LIVMARLI LONG-TERM FOLLOW-UP STUDY

What the MERGE study tells us about patients
treated with LIVMARLI for up to 7 years



Patients with Alagille syndrome were treated with LIVMARLI in 3 separate clinical studies called **ICONIC**, **IMAGINE**, and **IMAGINE-II**. Some patients in those studies continued treatment for up to 7 years.



The **MERGE** study followed up with 86 patients from **ICONIC**, **IMAGINE**, and **IMAGINE-II** to evaluate the long-term efficacy and safety of LIVMARLI in people with Alagille syndrome. The study included data from **23 patients who remained on treatment for 7 years.***

The study assessed changes in:



Cholestatic pruritus



Serum bile acids (sBA)



Growth (height and weight)



Bilirubin levels



Liver enzymes (ALT and AST)

ALT=alanine aminotransferase; AST=aspartate aminotransferase.

*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.

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

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

Measuring cholestatic pruritus and serum bile acids (sBA) over time

About the studies evaluated in MERGE

Previous studies of LIVMARLI in patients with Alagille syndrome evaluated improvements in cholestatic pruritus (itch) and sBA levels.[†]

- In a 48-week clinical study of 31 patients (called “ICONIC”), those taking LIVMARLI saw improvements lasting up to 4 years[‡]
- In 2 additional 72-week clinical studies of 53 patients (called “IMAGINE” and “IMAGINE-II”), those taking LIVMARLI saw improvements lasting through the end of the studies[§]
- Some patients in these previous studies also saw improvements in sBA levels
- The most commonly reported side effects in these 3 studies were gastrointestinal (GI) events like diarrhea, stomach pain, or vomiting. Other common side effects included fat-soluble vitamin (FSV) deficiency, liver test abnormalities, and bone fractures



What the MERGE study showed



Improvements in cholestatic pruritus

In the studies, 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.



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



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.



At 7 years, 14 out of 16 patients (88%) who had experienced cholestatic pruritus improvements after starting LIVMARLI still felt significant relief^{||}



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.

[‡]Patients included in the ICONIC study were between 1 and 18 years old.

[§]IMAGINE and IMAGINE-II were long-term continuations of studies called IMAGO and ITCH, respectively. Patients included in the studies were between 2 and 18 years old.

^{||}A total of 23 patients were evaluated for cholestatic pruritus improvements at 7 years.

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. 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 mucus
 - dizziness
 - severe stomach-area pain or tenderness
 - headache

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What study data tell us about additional benefits over time

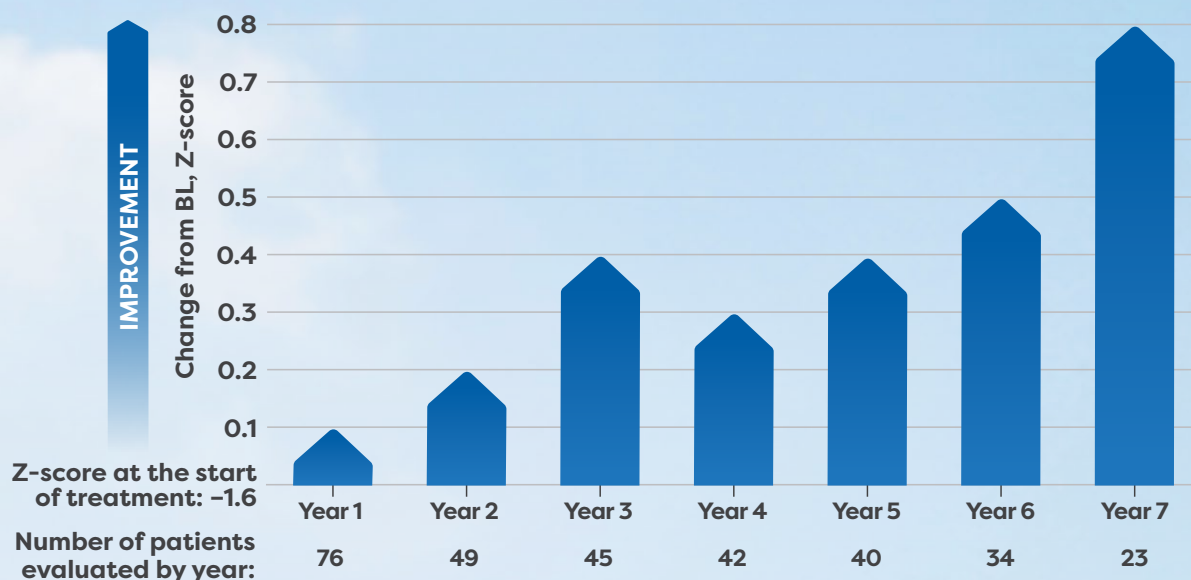


Changes in growth (height and weight)

Children with conditions that cause cholestatic pruritus can sometimes experience poor growth (shorter stature and decreased weight). Results from the MERGE study show that **patients who saw a reduction in cholestatic pruritus 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.

Changes in height from start of treatment[†]



Patients also gained weight within the first year of treatment with LIVMARLI. Improvements in both height and weight continued through 7 years.[#]

BL=baseline.

[†]Changes in height and weight were measured against the average patient Z-score at the start of treatment (average Z-score: -1.6).

[#]A total of 23 patients remained on treatment at year 7.

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.

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.

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

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The importance of bilirubin, ALT, and AST monitoring

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



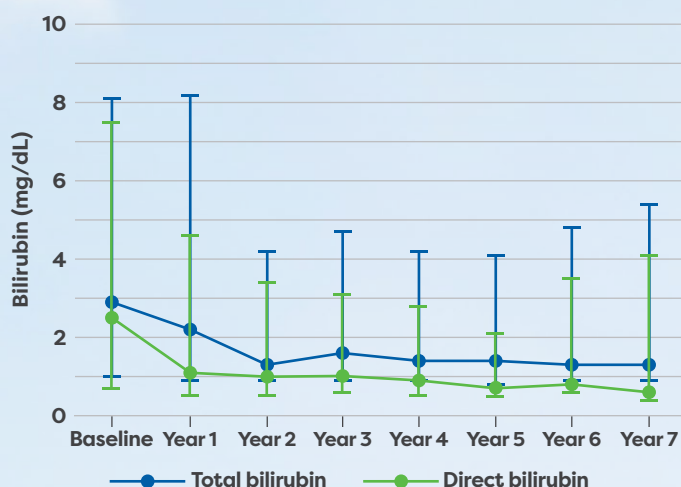
Bilirubin forms when your body breaks down red blood cells and they're removed from the liver in bile. If bile is not flowing properly, bilirubin can build up in the blood.



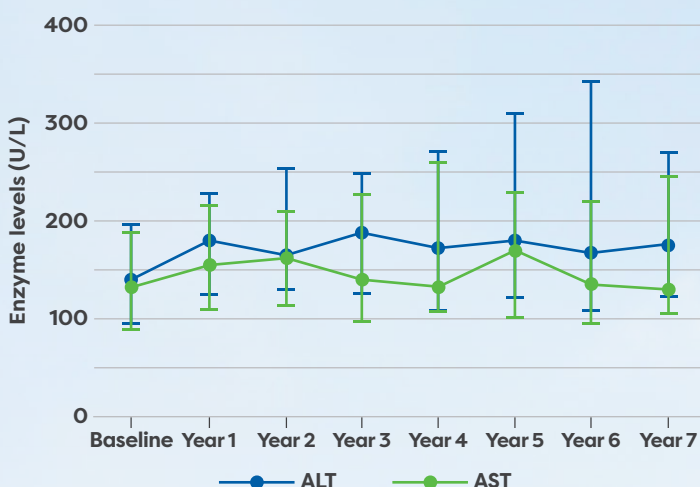
ALT and AST are liver enzymes that help process proteins and are measured to assess liver function. When liver cells are damaged or inflamed, these enzymes can leak into the bloodstream, causing higher levels of ALT and AST in the blood.

Liver function over time with LIVMARLI

Total and direct bilirubin over time



ALT and AST over time



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.**

Learn more about LIVMARLI at [LIVMARLI.com](https://www.livmarli.com)

ALT=alanine aminotransferase; AST=aspartate aminotransferase.

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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