# FDA APPROVED FOR 12 MONTHS OLD+ IN PFIC

LIVMARLI is a **liquid medicine** that is now approved in a new strength for patients with cholestatic pruritus (itch) in PFIC

LIVMARLI is indicated for the treatment of cholestatic pruritus in patients with progressive familial intrahepatic cholestasis (PFIC) who are 12 months of age and older.

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



#### 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.



#### **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**

Mirum Access Plus offers **resources**, **education**, **and services** to help you start and stay on LIVMARLI.

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.

#### INDICATION

LIVMARLI is a 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.

Please see Important Safety Information on following page and full <u>Patient Information</u>.



## LIVMARLI PROVIDES MEANINGFUL IMPROVEMENTS

in cholestatic pruritus (itch) for patients with progressive familial intrahepatic cholestasis (PFIC)

### Learn more at LIVMARLI.com

#### **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 with PFIC but may worsen during treatment. These changes may be a sign of liver injury and can be serious or may lead to 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
- 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
- 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 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

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 with LIVMARLI if you have certain side effects.

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 full Patient Information.



