Have you heard the news? LIVMARLI is...

NOW APPROVED FOR 12 MONTHS OLD+ IN PFIC

Livmarli® (maralixibat) oral solution

LIVMARLI is a **liquid formulation** that is now FDA approved in a new strength (19 mg/mL) for patients with cholestatic pruritus in PFIC[1]

LIVMARLI is indicated for the treatment of cholestatic pruritus in patients 12 months of age and older with progressive familial intrahepatic cholestasis (PFIC).[1]

Limitations of Use: LIVMARLI is not recommended in a subgroup of PFIC type 2 patients with specific *ABCB11* variants resulting in nonfunctional or complete absence of bile salt export pump (BSEP) protein.

The broadest population of PFIC subtypes studied[1-3]

Meaningful improvements in cholestatic pruritus were seen as early as 2 weeks and sustained through 2 years[1,3,4]

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Exceptional access and patient support

Please see Important Safety Information on following page and full Prescribing Information.

To find out how LIVMARLI can help your patients,

CONTACT YOUR REGIONAL ACCOUNT MANAGER

To learn more, visit LIVMARLIhcp.com

INDICATION

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

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IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

LIVMARLI is contraindicated in patients with prior or active hepatic decompensation events (eg, variceal hemorrhage, ascites, or hepatic encephalopathy).

WARNINGS AND PRECAUTIONS

Hepatotoxicity: LIVMARLI treatment is associated with a potential for drug-induced liver injury (DILI).

In the PFIC trial, treatment-emergent hepatic decompensation events and elevations of liver tests or worsening of liver tests occurred. Two patients experienced DILI attributable to LIVMARLI. Two additional patients experienced DILI in the open-label extension portion of the trial. Of these 4 patients, 1 patient required liver transplant and another patient died.

Obtain baseline liver tests and monitor during treatment. Liver-related adverse reactions and physical signs of hepatic decompensation should also be monitored. Dose reduction or treatment interruption may be considered if abnormalities occur in the absence of other causes. Permanently discontinue LIVMARLI if a patient experiences the following: persistent or recurrent liver test abnormalities, clinical hepatitis upon rechallenge, or a hepatic decompensation event.

Gastrointestinal (GI) Adverse Reactions: Diarrhea and abdominal pain were reported as the most common adverse reactions. Monitor for dehydration and treat promptly. Consider reducing the dosage or interrupting LIVMARLI dosing if a patient experiences persistent diarrhea or diarrhea with bloody stool, vomiting, dehydration requiring treatment, or fever.

Fat-Soluble Vitamin (FSV) Deficiency: Patients can have FSV deficiency (vitamins A, D, E, and K) at baseline, and LIVMARLI may adversely affect absorption of FSVs. Treatment-emergent bone fracture events have been observed more frequently with patients treated with LIVMARLI compared with patients treated with placebo. If bone fractures or bleeding occur, consider interrupting LIVMARLI and supplement with FSVs. LIVMARLI can be restarted once FSV deficiency is corrected and maintained at corrected levels.

Risk of Propylene Glycol Toxicity (Pediatric Patients Less Than 5 Years of Age): Total daily intake of propylene glycol should be considered for managing the risk of propylene glycol toxicity. Monitor patients for signs of propylene glycol toxicity. Discontinue LIVMARLI if toxicity is suspected.

ADVERSE REACTIONS

The most common adverse reactions are diarrhea, FSV deficiency, abdominal pain, liver test abnormalities, hematochezia, and bone fractures.

DRUG INTERACTIONS

Administer bile acid binding resins at least 4 hours before or 4 hours after administration of LIVMARLI.
A decrease in the absorption of OATP2B1 substrates (eg, statins) due to OATP2B1 inhibition by LIVMARLI in the GI tract cannot be ruled out. Consider monitoring the drug effects of OATP2B1 substrates as needed.

DOSING INFORMATION

LIVMARLI should be taken twice daily 30 minutes before a meal. The provided oral dosing dispenser must be used to accurately measure the dose. Any remaining LIVMARLI should be discarded 100 days after first opening the bottle.

Please see full Prescribing Information.

References: 1. LIVMARLI® (maralixibat) oral solution. Prescribing Information. Mirum Pharmaceuticals, Inc. **2.** Data on file. REF-01126. Mirum Pharmaceuticals, Inc. **3.** Miethke AG, Moukarzel A, Porta G, et al. Maralixibat in progressive familial intrahepatic cholestasis (MARCH-PFIC): a multicentre, randomised, double-blind, placebo-controlled, phase 3 trial. *Lancet Gastroenterol Hepatol.* 2024;9(7):620-631. doi:10.1016/S2468-1253(24)00080-3 **4.** Miethke A, Moukarzel A, Porta G, et al. Long-term maintenance of response and improved liver health with maralixibat in patients with progressive familial intrahepatic cholestasis (PFIC): 2-year data from the MARCH-ON study. Presented at: American Association for the Study of Liver Diseases (AASLD) The Liver Meeting: November 10-14, 2023; Boston, MA.

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