# HOW TO TALK WITH YOUR DOCTOR ABOUT LIVMARLI

# A Guide for Caregivers and People With Cholestatic Pruritus (Itch) in Alagille Syndrome

Itch caused by liver disease—also known as cholestatic pruritus—is one of the most burdensome symptoms of Alagille syndrome.

Itch can impact daily life in many ways. At times, it may be difficult to talk openly with your doctor about the challenges of the itch.

If you or your child are unsatisfied with your current treatment for itching or are ready to start treatment for the itch, use this guide to help you explain how itch affects you and your family, and whether LIVMARLI may be right for you or your child.



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

# 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



# **What Your Doctor Should Know About the Itch**

When it comes to assessing itch, doctors may only be looking for things like red marks, scratches, and open wounds. But these signs of the itch may not tell the full story. That's why it's important to describe the other ways that itch impacts you and your family. When you share more details, your doctor can make a more accurate assessment.



Ready	to	<b>Assess</b>	the	Itch
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When it's time to speak with your doctor, consider sharing answers to the following questions.

In what ways does itching impact...

- Your child's and/or your daily life:
- Falling asleep and/or staying asleep:
- Family life and/or relationships with friends and family:
- School, work, and/or home life:
- Playtime with friends and/or participation in activities:
- Mood and/or behavior:
- Additional impacts:

# **IMPORTANT SAFETY INFORMATION** (cont'd)

• 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

Notes:					





# What Your Doctor Should Know About the Itch

1111	How often does itcl	hing impact daily life?		How much relief do yo from your current itch	ou or your child get h treatment?
	Every day	1 to 2 times per month		Complete relief	I don't know
	1 to 2 times per week	Never		Some relief	I am not currently
	3 to 4 times pe	r week		No relief at all	treating my itch
	Do you and/or your	child use work-arounds	for the	itch? If yes, check all t	hat apply.
	Wearing mitter	ns to avoid scratches		Leeping baths and shov	vers short
	Avoiding hot te	mperatures	$\bigcirc$ $\iota$	Jsing cool or lukewarm	water when bathing
	Using lotions fo	r the itch		woiding certain clothin	g
	C Keeping fingerr	nails short	$\bigcirc$ (	Other:	
	What might improv	rement in the itch mean	for you	or your child?	



If you or your child is experiencing frequent, disruptive itching, there may be more that can be done. Discuss the itch with your doctor. **Together**, you can explore your treatment options.

# **IMPORTANT SAFETY INFORMATION (cont'd)**

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



CHECK IT. CHART IT. DISCUSS IT.

Logging your symptoms can help your doctor better assess the itch and see if treatment is working. If you haven't been recording your itch, that's OK. You can talk to your doctor about symptoms that you're currently experiencing.

Download the **Itch√** app today.

Available for iPhone® and Android™ devices.









No smartphone? No problem.

For a printable journal that you can fill out and share with your doctor, visit our resources.

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Please see Important Safety Information throughout and full <u>Patient Information</u>.

# **Working Together to Manage the Itch**

If you or your child are ready to start treatment or are unsatisfied with the way the itch is currently being managed, you may be a candidate for LIVMARLI.

LIVMARLI is an **FDA-approved treatment** that can improve the itch for people with Alagille syndrome who are 3 months of age and older.

To make the most of your appointment time, consider asking the following questions during your next visit:



### **About LIVMARLI**

- Could LIVMARLI be an option for me or my child?
- How does LIVMARLI work?
- How is LIVMARLI taken?
- How long could it take for LIVMARLI to work?
- How can I know if LIVMARLI is working?



# Safety

- What are the possible side effects of LIVMARLI?
- How can they be managed?
- Can LIVMARLI be taken if I or my child have other health conditions or take other medicines?
- Where can I find information on previous clinical trials?



## Monitoring

- How is progress monitored?
- Are lab tests needed to monitor progress while taking LIVMARLI?
- If yes, which ones?



# Support

- How do I get LIVMARLI?
- What support is available to help me or my child?





# **IMPORTANT SAFETY INFORMATION** (cont'd)

• 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.





# **IMPORTANT SAFETY INFORMATION** (cont'd)

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.

Please see Important Safety Information throughout and full <u>Patient Information</u>.



