GILEAD | Medical Information

Livdelzi® (seladelpar) Use in Pediatric Patients

This document is in response to your request for information regarding the use of Livdelzi® (seladelpar [SEL]) for the treatment of primary biliary cholangitis (PBC) in pediatric patients.

Some data may be outside of the US FDA-approved prescribing information. In providing this data, Gilead Sciences, Inc. is not making any representation as to its clinical relevance or to the use of any Gilead product(s). For information about the approved conditions of use of any Gilead drug product, please consult the FDA-approved prescribing information.

The full indication, important safety information, and boxed warnings are available at: www.gilead.com/-/media/files/pdfs/medicines/pbc/livdelzi/livdelzi_pi.

Product Labeling[1]

The safety and effectiveness of SEL in pediatric patients have not been established.

Clinical Data on the Use of SEL in Pediatric Patients

No clinical study data are available on the use of SEL in pediatric patients.

Literature Search on SEL Use in Pediatric Patients

A literature search was conducted in Ovid MEDLINE and Embase databases for studies published up to September 23, 2025, using the search terms Livdelzi, seladelpar, pediatrics, child, youth, and related search terms. No relevant citations were identified.

Reference

1. Enclosed. LIVDELZI® (seladelpar) capsules, for oral use. US Prescribing Information. Foster City, CA.

Product Label

For the full indication, important safety information, and boxed warning(s), please refer to the Livdelzi US Prescribing Information available at: www.gilead.com/-/media/files/pdfs/medicines/pbc/livdelzi/livdelzi_pi.

Follow-Up

For any additional questions, please contact Gilead Medical Information at:

☎1-866-MEDI-GSI (1-866-633-4474) or 🖱 www.askgileadmedical.com

Adverse Event Reporting

Please report all adverse events to:

Gilead Global Patient Safety ☎ 1-800-445-3235, option 3 or
🖱 www.gilead.com/utility/contact/report-an-adverse-event

FDA MedWatch Program by ☎ 1-800-FDA-1088 or ✉MedWatch, FDA, 5600 Fishers Ln, Rockville, MD 20852 or 🖱 www.accessdata.fda.gov/scripts/medwatch

Data Privacy

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