GILEAD | Medical Information

Livdelzi® (seladelpar) Use During Pregnancy or Breastfeeding

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 individuals who are pregnant or breastfeeding.

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]

Use in Specific Populations

Pregnancy

Risk summary

There are insufficient data from human pregnancies exposed to SEL to allow an assessment of a drug-associated risk of major birth defects, miscarriage, or other adverse maternal or fetal outcomes. In animal reproduction studies, no malformations or effects on embryo-fetal survival occurred in pregnant rats or rabbits after SEL treatment at exposures of up to 176-times and 49-times the recommended dose based on area under the plasma concentration-time curve (AUC), respectively. Reduction of fetal growth associated with maternal toxicity occurred in pregnant rabbits at 49-times the recommended dose based on AUC, but not at 3-times the recommended dose. In a pre- and postnatal development study in rats with maternal dosing of SEL during organogenesis through lactation, postnatal growth and preweaning survival of offspring was reduced at 115-times the recommended dose based on AUC, but not at the lower exposure of 16-times the recommended dose.

The background risks of major birth defects and miscarriage for the indicated population are unknown. All pregnancies have a background risk of birth defect, loss, or other adverse outcomes. In the US general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2% to 4% and 15% to 20%, respectively.

Report pregnancies to Gilead Sciences, Inc. at 1-800-445-3235.

Lactation

Risk summary

There are no data on the presence of SEL or its metabolite in either human or animal milk, the effects on the breastfed infant, or the effects on milk production. The developmental and

health benefits of breastfeeding should be considered along with the mother's clinical need for SEL and any potential adverse effects on the breastfed infant from SEL or from the underlying maternal condition.

Clinical Data on SEL Use During Pregnancy or Breastfeeding

No clinical study data are available on the use of SEL in pregnant or breastfeeding participants.

Participants who were pregnant or breastfeeding were excluded from pivotal clinical studies of SEL use in participants with PBC.[2-5]

Literature Search on SEL Use During Pregnancy or Breastfeeding

A literature search was conducted in Ovid MEDLINE and Embase databases for studies published up to September 9, 2026, using the search terms Livdelzi, seladelpar, pregnancy, lactation, breastfeeding, and related search terms. No relevant citations were identified.

References

1. Enclosed. LIVDELZI® (seladelpar) capsules, for oral use. US Prescribing Information. Foster City, CA.
2. Hirschfield GM, Bowlus CL, Mayo MJ, et al. A Phase 3 Trial of Seladelpar in Primary Biliary Cholangitis. *N Engl J Med.* 2024;390(9):783-794.
3. Hirschfield GM, Bowlus CL, Mayo MJ, et al. A Phase 3 Trial of Seladelpar in Primary Biliary Cholangitis.[Supplementary Appendix]. *N Engl J Med.* 2024;390(9):783-794.
4. Hirschfield GM, Shiffman ML, Gulamhusein A, et al. Seladelpar efficacy and safety at 3 months in patients with primary biliary cholangitis: ENHANCE, a phase 3, randomized, placebo-controlled study. *Hepatology.* 2023;78(2):397-415.
5. ClinicalTrials.gov. ENHANCE: Seladelpar in Subjects With Primary Biliary Cholangitis (PBC) and an Inadequate Response to or an Intolerance to Ursodeoxycholic Acid (UDCA). Available at: https://clinicaltrials.gov/study/NCT03602560.

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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