Livdelzi® (seladelpar)
Use in Patients With Autoimmune Hepatitis and Primary Biliary Cholangitis Overlap

This document is in response to your request for information regarding the use of Livdelzi® (seladelpar [SEL]) in patients with autoimmune hepatitis (AIH) or AIH overlap with primary biliary cholangitis (AIH-PBC).

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]

Indications and Usage

SEL is indicated for the treatment of PBC in combination with ursodeoxycholic acid (UDCA) in adults who have had an inadequate response to UDCA, or as monotherapy in patients unable to tolerate UDCA.

This indication is approved under accelerated approval based on a reduction of alkaline phosphatase. Improvement in survival or prevention of liver decompensation events have not been demonstrated. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trial(s).

Limitations of use: Use of SEL is not recommended in patients who have or develop decompensated cirrhosis (eg, ascites, variceal bleeding, hepatic encephalopathy).

Clinical Data on SEL Use in Patients With AIH or AIH-PBC Overlap

Currently, there are no clinical data or guidance on the use of SEL in patients with AIH or AIH-PBC overlap. In the completed and ongoing SEL phase 3 trials RESPONSE, ENHANCE, and AFFIRM, AIH (which would also include AIH-PBC overlap) was an exclusion criteria.[2-4]

Additionally, a literature search was conducted in Ovid MEDLINE and Embase databases for studies published up to January 12, 2026, using search terms that included Livdelzi, seladelpar, autoimmune hepatitis, AIH-PBC overlap, and related search terms. No relevant citations were found.

References

1. Enclosed. Gilead Sciences Inc. 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, 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.
4. ClinicalTrials.gov. Seladelpar in Subjects With Primary Biliary Cholangitis (PBC). Available at: https://clinicaltrials.gov/study/NCT03301506?term=NCT03301506&rank=1. Accessed: January 2026. Last Updated: 12 December 2025.

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

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