

Livdelzi® (seladelpar)

Coadministration with Alcohol

This document is in response to your request for information regarding Livdelzi® (seladelpar [SEL]) and coadministration with alcohol.

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: https://www.gilead.com/-/media/files/pdfs/medicines/pbc/livdelzi/livdelzi_pi.pdf

PK DDI Evaluation

Drug interaction studies have not been conducted between SEL and alcohol. Based on the PK profile of each active ingredient within SEL and alcohol, a PK interaction would not be predicted.¹

SEL PK¹

DDI Mechanism		SEL
Drug Transporters	P-gp/BCRP	Substrate
	OATP1B1	N/A
	OATP1B3	N/A
	OAT3	Substrate
	MATE-1	N/A
	MATE2-K	N/A
	OAT1	N/A
	OCT1	N/A
	OCT2	N/A
Drug Metabolizing Enzymes	CYP1A2	N/A
	CYP2B6	N/A
	CYP2C8	Substrate
	CYP2C9	Substrate
	CYP2C19	N/A
	CYP2D6	N/A
	CYP3A4	Substrate

Relevant SEL Label Information¹

There is no information in the SEL product labeling about the coadministration of SEL and alcohol. For more information, please refer to Section 7 of the SEL US Prescribing Information (Drug Interactions).

Available Data

There are no Gilead studies evaluating the coadministration of SEL and alcohol.

In the RESPONSE study clinically important alcohol consumption, defined as more than 2 drink units per Day (equivalent to 20 g) in women and 3 drink units per Day (equivalent to 30 g) in men, or inability to quantify alcohol intake reliably was an exclusion criteria.²

Additionally, a literature search was conducted in Ovid MEDLINE and Embase databases for studies published between 1946 and May 9, 2025 using search terms that included Livdelzi, seladelpar, alcohol, and related search terms. The following citations were identified.

- Chu H, Jiang L, Gao B, et al. The selective PPAR-delta agonist seladelpar reduces ethanol-induced liver disease by restoring gut barrier function and bile acid homeostasis in mice. *Transl Res.* 2021;227doi:10.1016/j.trsl.2020.06.006
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References

1. Enclosed. LIVDELZI® (seladelpar) capsules, for oral use. US Prescribing Information. Foster City, CA.
 2. 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.
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Abbreviations

BCRP=breast cancer
resistance protein

DDI=drug-drug interaction

MATE=multidrug and toxic
compound extrusion

OAT=organic anion
transporter

OATP=organic anion
transporting polypeptide

OCT=organic cation
transporter

P-gp=P-glycoprotein

PK=pharmacokinetic(s)

SEL=seladelpar

Product Label

For the full indication, important safety information, and Boxed Warning(s), please refer to the Epclusa US Prescribing Information available at:

https://www.gilead.com/-/media/files/pdfs/medicines/pbc/livdelzi/livdelzi_pi.pdf

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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