GILEAD | Medical Information

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

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 PK[1]

Table 1. SEL PK[1]

DDI Mechanism		SEL
Drug Transporters	P-gp/BCRP	Substrate
	OATP1B1	Substrate
	OATP1B3	Substrate
	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[a]	Substrate
	CYP2C19	N/A
	CYP2D6	N/A
	CYP3A4	Substrate

[a]Primary metabolizer.

Relevant SEL Label Information[1]

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 on SEL Coadministration With Alcohol

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

In the RESPONSE study, clinically important alcohol consumption, defined as >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 up to 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;227:1–14. doi: 10.1016/j.trsl.2020.06.006

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.

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 Livzelzi 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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