

Livdelzi[®] (seladelpar)

Coadministration With Budesonide

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

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 budesonide. Based on the PK profile of each active ingredient within SEL and budesonide, a PK interaction would not be predicted.^{1,2} For more information about budesonide, please refer to its product labeling.²

SEL PK¹

Table 1. SEL PK¹

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

^aPrimary metabolizer.

Relevant SEL Label Information¹

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

Available Data on SEL Coadministration With Budesonide

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

Additionally, a literature search was conducted in Ovid MEDLINE and Embase databases for studies published up to June 13, 2025, using search terms that included Livdelzi, seladelpar, budesonide, and related search terms. No relevant citations were found.

References

1. Enclosed. LIVDELZI® (seladelpar) capsules, for oral use. US Prescribing Information. Foster City, CA.
 2. PULMICORT RESPULES® (budesonide inhalation suspension). US Prescribing Information. Wilmington, DE.
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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 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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