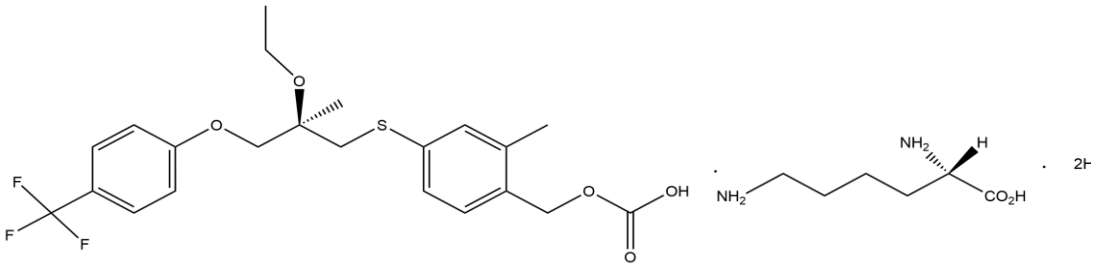
Seladelpar PK Fact Sheet

Details

Generic Name	Seladelpar
Trade Names	Livdelzi®, Lyvdelzi®
Class	PBC agents
Molecular Weight	626.7
Structure	

Summary of Key Pharmacokinetic Parameters

Linearity/non-linearity	Seladelpar exposure increased dose proportionally between 2 mg – 15 mg and greater than proportionally at higher doses.
Steady state	During once daily dosing, steady state for seladelpar was reached by 4 days.
Plasma half-life	3.8 -6.7 h in PBC patients.
Cmax	103 (29.3) ng/mL (SD), once daily dosing 10 mg, in PBC patients.
C24	Not reported.
AUC	902 (938) ng·h/mL (SD), once daily dosing 10 mg, in PBC patients.
Bioavailability	Not reported.
Absorption	No clinically significant differences when seladelpar was administered with a high-fat meal. T_{max} 1.5 h. Seladelpar can be administered without regard to food.
Protein Binding	>99%
Volume of Distribution	133.2 L
Renal Clearance	73.4%
Renal Impairment	No dose modification required for mild, moderate, or severe renal impairment. Patients on dialysis have not been studied.
Hepatic Impairment	No dose modification required for mild (Child-Pugh class A) hepatic impairment. Safety and efficacy have not been established in patients with decompensated cirrhosis and use is not recommended. Monitor patients with cirrhosis for decompensation. Consider discontinuing seladelpar in patients who develop moderate or severe (Child-Pugh class B or C) hepatic impairment.

Metabolism and Distribution

Metabolized by	CYP2C9, CYP2C8, CYP3A4.
Inducer of	Did **not** induce CYP1A2, CYP2B6, or CYP2C8 *in vitro.*
Inhibitor of	Did **not** inhibit CYP1A2, 2B6, 2C8, 2C19, 2D6, 3A4, UGTs, P-gp, MATE1, MATE-2K, OCT1, OCT2, OAT1, or OAT3 *in vitro.*
Transported by	BCRP, P-gp, OAT3.

References

Unless otherwise stated (see below), information is from:

Livdelzi Prescribing Information, Gilead Sciences Inc, August 2024.

Livdelzi Summary of Product Characteristics, Gilead Sciences Ltd, January 2025.