



Livdelzi[®] (seladelpar)

Opening or Splitting Capsules

This document is in response to your request for information regarding Livdelzi[®] (seladelpar [SEL]) and opening or splitting capsules.

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 Labeling¹

There is no information in the SEL product labeling about the opening or splitting of SEL capsules; therefore, it is not recommended that SEL be administered as an opened or split capsule.

The solubility of SEL in water is pH dependent. It is slightly soluble at low pH and very soluble at high pH.

Clinical Data on Opening or Splitting SEL Capsules

Gilead Data²

Opening SEL capsules and adding into a liquid medium has not been studied and is not recommended. Currently, there are no studies evaluating the pharmacokinetics (eg, oral bioavailability) of an opened SEL capsule dispersed into a liquid medium (eg, milk, water, juice) compared with a whole capsule.

Similarly, splitting SEL capsules has not been studied, and it is not recommended. Currently, there is no study evaluating the pharmacokinetics of a split capsule versus a whole capsule.

Literature Search

A literature search was conducted in Ovid MEDLINE and Embase databases for studies published up to January 21, 2026, using the search terms seladelpar and opening, cutting, breaking, splitting capsules, and related search terms. No relevant citations were identified.

References

1. Enclosed. LIVDELZI[®] (seladelpar) capsules, for oral use. US Prescribing Information. Foster City, CA.
2. Gilead Sciences Inc. Data on File.

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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