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GILEAD | Medical Information

Livdelzi® (seladelpar) Storage and Stability

This document is in response to your request for extended storage and stability information of Livdelzi® (seladelpar [SEL]) 10 mg capsules and does not intend to offer an opinion regarding the clinical relevance of these data or the advisability of storing or administering any drug in a manner inconsistent with its approved labeling. Livdelzi® (SEL) should be stored according to the product label.

The full indication, important safety information, and boxed warnings are available at: www.gilead.com/-/media/files/pdfs/medicines/pbc/livdelzi/livdelzi_pi.

Product Labeling[1]

Each high-density polypropylene bottle contains 30 capsules and is closed with a polypropylene child-resistant cap containing an induction seal.

Store at 20°C to 25°C (68–77°F); excursions permitted to 15°C to 30°C (59–86°F).

Dispense only in original container to protect from light.

Alternative Storage and Stability Information[2]

The table below summarizes available data from in-house studies regarding the storage of SEL capsules in varying conditions. The “acceptable duration” refers to the stability of SEL capsules in the specified packaging and storage condition, but it does not endorse alternative packaging or use beyond the expiration date stated on the original packaging.

Table 1. Summary of Extended Stability Data for SEL Capsules[2]

Storage Condition	Package Type	Acceptable Duration
25°C (77°F)/60% relative humidity[a]	Original bottle in-use[a]	30 days
5°C (41°F)	Original sealed bottle	3 months
40°C (104°F)/75% relative humidity	Original sealed bottle	1 month
50°C (122°F)/ambient relative humidity	Original sealed bottle	7 days
Freeze/thaw for 3 cycles with 1 day at -20°C (-4°F) and 1 day at 25°C (77°F)/60% relative humidity as 1 cycle	Original sealed bottle	3 days at -20°C (-4°F)

[a]In-use testing conditions, defined as bottle opened and one capsule removed daily.

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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