



Zydelig[®] (idelalisib)

Storage and Stability

This document is in response to your request for extended storage and stability information of Zydelig[®] (idelalisib) 150 mg and 100 mg tablets 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. Zydelig[®] (idelalisib) should be stored according to the product label.

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/oncology/zydelig/zydelig_pi.

Product Labeling¹

Each bottle contains 60 film-coated tablets and is packaged in a high-density polyethylene bottle with a polyester fiber coil, capped with a child-resistant closure.

Store between 20°C and 30°C (68–86°F) with excursions permitted to 15°C to 30°C (59–86°F).

Dispense only in original container.

Do not use if seal over bottle opening is broken or missing.

Alternative Storage and Stability Information²

The table below summarizes available data from in-house studies regarding the storage of idelalisib tablets in varying conditions. The “acceptable duration” refers to the stability of idelalisib tablets 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 Idelalisib Tablets²

Storage Condition	Package Type	Acceptable Duration
Open dish 25°C (77°F)/60% relative humidity	Open petri dish ^a	60 days
Open dish 30°C (86°F)/75% relative humidity	Open petri dish ^a	60 days
40°C (104°F)/75% relative humidity	Original sealed bottle	6 months
-20°C (-4°F)	Original sealed bottle	60 days
5°C (41°F)	Original sealed bottle	60 days
60°C (140°F)	Original sealed bottle	60 days

^aTablets were stored outside of their commercial packaging configuration in an open petri dish.

References

1. Enclosed. Gilead Sciences Inc, ZYDELIG® (idelalisib) tablets, 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 Zydelig US Prescribing Information available at:

www.gilead.com/-/media/files/pdfs/medicines/oncology/zydelig/zydelig_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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