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Bixlenvo™ (bictegravir/lenacapavir) Storage and Stability

This document is in response to your request for extended storage and stability information of Bixlenvo™ (bictegravir/lenacapavir [BIC/LEN]) 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. Bixlenvo™ (BIC/LEN) 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/hiv/BIXLENVO/BIXLENVO_pi.

Product Labeling[1]

How Supplied/Storage and Handling

BIC/LEN tablets are supplied in bottles. Dispense and store only in the original bottle to protect from moisture.

Each bottle contains 30 tablets, a silica gel desiccant and is closed with a child-resistant closure. Do not remove the desiccant canister.

Store BIC/LEN tablets at 20 °C to 25 °C (68 °F to 77 °F), excursions permitted between 15°C to 30°C (59 °F to 86 °F). Keep bottles tightly closed.

Alternative Storage and Stability Information[2]

The table below summarizes available data from in-house studies regarding the storage of BIC/LEN tablets in varying conditions. The “acceptable duration” refers to the stability of BIC/LEN 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 BIC/LEN 75 mg/50 mg Tablets[2]

Storage Condition	Package Type	Acceptable Duration
40 °C (104 °F)/75% RH	Original Bottle	6 months
50 °C (122 ºF)/ambient RH[a]	Original Bottle	2 weeks
-20 °C (-4 °F)	Original Bottle	1 month
Open dish, 25 °C (77 °F)/60% RH[b]	Open petri dish	3 months
Open dish, 30 °C (86 °F)/75% RH[b]	Open petri dish	1 month
30 °C (86 °F)/75% RH	Original Bottle in-use[c] with desiccant	30 days

Abbreviation: RH=relative humidity.
[a]Humidity is not controlled or measured.
[b]Tablets are stored outside of the commercial packaging configuration in an open petri dish.
[c]In-use=bottle opened, and one tablet removed daily.

References

1. Enclosed, Gilead Sciences Inc. BIXLENVO™ (bictegravir and lenacapavir) tablets, for oral use. U.S. 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 Bixlenvo US Prescribing Information available at: https://www.gilead.com/-/media/files/pdfs/medicines/hiv/BIXLENVO/BIXLENVO_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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