GILEAD | Medical Information

Tybost® (cobicistat) Storage and Stability

This document is in response to your request for extended storage and stability information of Tybost® (cobicistat [COBI]) 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. Tybost® (COBI) 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/hiv/tybost/tybost_pi.

Product Labeling[1]

Each bottle contains 30 tablets and a silica desiccant, with a child-resistant closure. Store at 25°C (77°F); excursions permitted to 15°C to 30°C (59–86°F). Keep container tightly closed. Dispense only in original container. Do not use if seal over bottle opening is broken or missing.

Alternative Storage and Stability Information[2]

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

Storage Condition	Package Type	Acceptable Duration
25°C (77°F)/60% relative humidity[a]	Open petri dish	6 weeks
-20°C (-4°F)	Original sealed bottle	7 days

[a]Tablets are stored outside of the commercial packaging configuration in an open petri dish.

References

1. Enclosed. Gilead Sciences Inc, TYBOST® (cobicistat) 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 Tybost US Prescribing Information available at: www.gilead.com/-/media/files/pdfs/medicines/hiv/tybost/tybost_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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