GILEAD | Medical Information

Biktarvy® (BIC/FTC/TAF) Storage and Stability

This document is in response to your request for extended storage and stability information of Biktarvy® (bictegravir/emtricitabine/tenofovir alafenamide [BIC/FTC/TAF]) 50 mg/200 mg/25 mg or 30 mg/120 mg/15 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. Biktarvy® (BIC/FTC/TAF) 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/biktarvy/biktarvy_pi.

Product Labeling[1]

How Supplied/Storage and Handling

BIC/FTC/TAF tablets are available in bottles and blister packs. Dispense only in original containers.

Bottle

Each bottle contains 30 tablets, a silica gel desiccant, polyester coil, and is closed with a child-resistant closure. Do not remove the desiccant packet. Store bottle below 30°C (86°F). Keep bottle tightly closed.

Blister Pack

Each blister pack contains 30 tablets (4 strips each containing 7 tablets and 1 strip containing 2 tablets). Blister packs are sealed with a child-resistant laminated foil lidding material (peel-push), and each blister cavity contains a die-cut desiccant film which is heat staked to the foil lidding material. Store blister pack at 25°C (77°F), excursions permitted to 15°C to 30°C (59–86°F).

Alternative Storage and Stability Information[2]

The tables below summarizes available data from in-house studies regarding the storage of BIC/FTC/TAF tablets in varying conditions. The “acceptable duration” refers to the stability of BIC/FTC/TAF 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/FTC/TAF 50 mg/200 mg/25 mg Tablets[2]

Storage Condition	Package Type	Acceptable Duration
25°C (77°F)/60% RH	Original bottle[a] in-use[b] with desiccant	30 days
30°C (86°F)/75% RH	Original bottle[a] in-use[b] with desiccant	30 days
40°C (104°F)/75% RH	Original sealed bottle[a]	6 months
50°C (122°F)/ambient RH[c]	Original sealed bottle[a]	1 week
-20°C (-4°F)	Original sealed bottle[a]	1 week
Open dish, 5°C (41°F)[d]	Open petri dish	42 days
Open dish, 25°C (77°F)/60% RH[d]	Open petri dish	1 day
Open dish, 30°C (86°F)/75%RH[d]	Open petri dish	0 days[e]
-20°C (-4°F)	Original Gilead blister[f]	4 weeks
50°C (122°F)	Original Gilead blister[f]	1 week

Abbreviation: RH=relative humidity.
[a]A 30-count bottle.
[b]In use=bottle opened, and one tablet removed daily.
[c]Humidity is not controlled or measured.
[d]Tablets are stored outside of the commercial packaging configuration in an open petri dish.
[e]Tablets did not meet required specifications when removed from the original container and placed in a petri dish for 1 day.
[f]The BIC/FTC/TAF blister pack incorporates customized design and technology specifically developed to incorporate features, including but not limited to individual desiccants in each blister cavity, to assure tablet stability. For this reason, stability data cannot be extrapolated to other blister packages.

Table 2. Summary of Extended Stability Data for BIC/FTC/TAF 30 mg/120 mg/15 mg Tablets[2]

Storage Condition	Package Type	Acceptable Duration
30°C (86°F)/75% RH	Original bottle[a] in-use[b] with desiccant	30 days
40°C (104°F)/75% RH	Original sealed bottle[a]	6 months
50°C (122°F)	Original sealed bottle[a]	2 weeks
-20°C (-4°F)	Original sealed bottle[a]	1 month

Abbreviation: RH=relative humidity.
[a]A 30-count bottle.
[b]In use=bottle opened, and one tablet removed daily.

References

1. Enclosed, Gilead Sciences Inc. BIKTARVY® (bictegravir, emtricitabine, and tenofovir alafenamide) 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 Biktarvy US Prescribing Information available at: www.gilead.com/-/media/files/pdfs/medicines/hiv/biktarvy/biktarvy_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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