

## Triumeq: Partial Dispensing, Unit-Dose Repackaging, and Temperature Stability

### Summary<sup>1</sup>

- *Triumeq* (abacavir/dolutegravir/lamivudine [ABC/DTG/3TC]) tablets should always be stored and dispensed in the original package. Do not remove the desiccant from the original package.
- ABC/DTG/3TC tablets are moisture-sensitive and the product stability is linked to the presence of moisture; therefore, ABC/DTG/3TC tablets should not be repackaged into unit-dose blister packs.
- Once opened, ABC/DTG/3TC tablets may be dispensed up to the expiration date that is stamped on the container, as long as the desiccant is present and still intact.
- ABC/DTG/3TC tablets should be stored at 25°C (77°F); excursions are permitted to 15° to 30°C (59° to 86°F). Additional data is available from in-house stability studies related to the temperature and relative humidity of packaged ABC/DTG/3TC tablets.
- Important safety information and boxed warning(s) can be found in the Prescribing Information and can also be accessed at [Our HIV Medicines](#).

To access additional scientific information related to ViiV Healthcare medicines, visit the ViiV US Medical Portal at [viivhcmmedinfo.com](http://viivhcmmedinfo.com).



ABC/DTG/3TC tablets should be stored and dispensed in the original package, protected from moisture, and with the bottle tightly closed. Do not remove the desiccant from the bottle.<sup>1</sup>

Once opened, ABC/DTG/3TC tablets may be dispensed up to the expiration date that is stamped on the container, as long as the desiccant is present and still intact.

ABC/DTG/3TC tablets are moisture-sensitive and the product stability is linked to the presence of moisture. ABC/DTG/3TC tablets should not be repackaged into unit-dose blister packages.

ViiV Healthcare cannot recommend the use of product that is stored or dispensed outside of the original packaging or product that has been stored without the desiccant.

### SUPPLEMENTAL STABILITY DATA

The following studies were conducted in high-density polyethylene (HDPE) bottles with child resistant closures and induction seal liners.<sup>2</sup> The bottles contained 30 tablets and included a two-gram silica gel desiccant. This container is identical to the commercial HDPE bottle used to ship and store ABC/DTG/3TC tablets.

## High Temperature Stability

Studies that evaluated temperature stability excursions for ABC/DTG/3TC showed that ABC/DTG/3TC was stable at 30° C (86° F) and 75% relative humidity for up to 36 months.<sup>2</sup> Further data indicated that temperatures of 40° C (104° F) / 75% relative humidity for up to 6 months and temperatures of 50° C (122° F) at ambient humidity for up to 3 months found no significant change in stability.

## Low Temperature Stability

A 28-day freeze-thaw study evaluated ABC/DTG/3TC under conditions of alternating freezing conditions of -20° C (-4° F) for seven days, then 30° C (86° F) for seven days (two cycles each), and found no significant change in stability.<sup>2</sup>

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**Some information contained in this response is outside the approved Prescribing Information.**

**This product is not approved for the use described. This response is not intended to offer recommendations for administering this product in a manner inconsistent with its approved labeling.**

**In order for ViiV Healthcare to monitor the safety of our products, we encourage healthcare professionals to report adverse events or suspected overdoses to the company at 877-844-8872. Please consult the attached Prescribing Information.**

**This response was developed according to the principles of evidence-based medicine and, therefore, references may not be all-inclusive.**



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## REFERENCES

1. ViiV Healthcare. Global Data Sheet for abacavir/dolutegravir/lamivudine, Version 0012, June 8, 2018.
2. Data on File. 2015N244026\_01.