Triumeq PD: Expiration Date, Partial Dispensing, Unit-Dose Repackaging, and Temperature Stability

Summary

- *Triumeq PD* (abacavir/dolutegravir/lamivudine [ABC/DTG/3TC] tablets for oral suspension) should always be stored and dispensed in the original package.[1] Do not remove the desiccant from the original package.
- *Triumeq PD* are moisture-sensitive and the product stability is linked to the presence of moisture; therefore, *Triumeq PD* should not be repackaged into unit-dose blister packs.
- Once opened, *Triumeq PD* may be dispensed up to the expiration date that is stamped on the container, as long as the desiccant is present and still intact.
- *Triumeq PD* should be stored at 20° C to 25° C (68° F to 86° F); excursions permitted between 15° C to 30° C (59° F to 86° F).[1] Additional, supplemental data is available.
- Important safety information and boxed warning(s) can be found in the Prescribing Information link 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 viivhcmedinfo.com.

EXPIRATION DATING, PARTIAL DISPENSING, AND TEMPERATURE STORAGE RECOMMENDATIONS

ViiV Healthcare cannot recommend the use of *Triumeq PD* tablets for oral suspension when stored outside of the following conditions:

Triumeq PD tablets for oral suspension are supplied in bottles of 90 tablets with a child-resistant closure containing a desiccant.[1] Each bottle is packaged with one 40-mL dosing cup. Store and dispense in the original package, protect from moisture, and keep the bottle tightly closed. Do not remove the desiccant from the bottle. *Triumeq PD* should be stored at 20° C to 25° C (68° F to 86° F); excursions permitted between 15° C to 30° C (59° F to 86° F).

Triumeq PD once opened may be dispensed up to the expiration date that is stamped on the container, as long as the desiccant is present and still intact.

UNIT DOSE REPACKAGING

Triumeq PD are moisture-sensitive and the product stability is linked to the presence of moisture. *Triumeq PD* should not be repackaged into unit-dose blister packages.

SUPPLEMENTAL STABILITY DATA

The following studies were conducted in high-density polyethylene (HDPE) bottles with child resistant closures and induction seal liners.[2] The bottles contained 90 tablets and included a two-gram silica gel desiccant. This container is identical to the commercial HDPE bottle used to ship and store *Triumeq PD*.

High and Low Temperature Stability

Studies that evaluated temperature stability excursions for *Triumeq PD* showed that stability was maintained at 30° C (86° F) and 75% relative humidity for up to 36 months.[2] 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.

A 28–day freeze-thaw study evaluated *Triumeq PD* 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.[2]

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.

REFERENCES

1. ViiV Healthcare Local Label.
2. Data on File. 2022N502233_00.