

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

Summary¹

- Once the original manufacturer's bottle is opened and some tablets are partially dispensed, the remaining tablets can be dispensed up to the expiration date stamped on the container when the original bottle is stored in accordance with the recommended temperature range described in the local label.
- Pharmacists should consult local pharmaceutical authorities regarding the expiration of medication dispensed from the manufacturer's stock bottle and repackaged into another container. This date should never exceed the expiration date on the original container and the tablets should be stored in accordance with the recommended temperature range described in the local label.
- There is currently no data on repackaging *Dovato* (dolutegravir/lamivudine [DTG/3TC]) tablets into unit-dose blister packages.
- Please refer to the local label storage requirements for DTG/3TC tablets.¹ Tablets should be stored below 30°C (86°F). Additional data is available from in-house stability studies related to the temperature and relative humidity of packaged DTG/3TC tablets.
- Important safety information and boxed warnings(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 UNIT-DOSE REPACKAGING

DTG/3TC tablets should not be used beyond the expiration date stated on the bottle label. If the original bottle is opened and some tablets are partially dispensed, the remaining tablets in the original bottle can be dispensed up to the expiration date stamped on the label, as long as the original bottle is stored below 30°C (86°F). The expiration dating of the partially dispensed tablets into a separate container should never exceed the expiration date on the original container. There is currently no data on repackaging DTG/3TC into unit-dose blister packages.

SUPPLEMENTAL TEMPERATURE STABILITY DATA

The decision to store DTG/3TC tablets in a manner outside of the local label recommendation is at the discretion of the health care professional.

The following studies were conducted in high-density polyethylene (HDPE) bottles with child resistant closures and induction seal liners.² The bottles contained 30 tablets. This container is similar to the one used for the commercial product.

High Temperature Stability

Studies that evaluated temperature stability excursions for DTG/3TC showed that DTG/3TC was stable at 30° C (86° F) and 75% relative humidity for up to 24 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.

Low Temperature Stability

A 1-month freeze-thaw study evaluated DTG/3TC under conditions of alternating freezing conditions of -20° C (-4° F) for 7 days, followed by 30° C (86° F) for 7 days (2 repeated cycles), and found no significant change in stability.²

Trademarks are owned by or licensed to the ViiV Healthcare group of companies.

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.



CLICK FOR **ViiV US**
Medical Portal

REFERENCES

1. ViiV Healthcare. Global Data Sheet for dolutegravir-lamivudine, Version 04, July 21, 2020.
2. Data on File. 2018N389443_00.