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

Summary[1]

- *Tivicay* (dolutegravir [DTG] 10 mg tablets and DTG PD 5 mg tablets for oral suspension: always store and dispense in the original package. Do not remove the desiccant from the original package. Do not repackage into blister or unit-dose packaging. Once opened, DTG 10 mg and DTG PD 5 mg 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.
- DTG 25 and DTG 50 mg tablets: 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 DTG 25 or 50 mg tablets 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 DTG 25 or 50 mg tablets into unit-dose blister packages. Do not repackage DTG 10 mg or DTG PD 5 mg tablets for oral suspension into unit-dose blister packages.
- Please refer to the local label storage requirements for DTG. Additional data is available from in-house stability studies related to the temperature and relative humidity of packaged DTG and DTG PD for oral suspension tablets.
- Important safety information 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 DTG or DTG PD tablets for oral suspension when stored outside of the following conditions:

DTG 10 mg tablets are supplied in bottles of 30 tablets with a desiccant. Store and dispense the 10-mg tablets in the original package, protect from moisture, and keep the bottle tightly closed. Do not remove desiccant. DTG 10 mg tablets should be stored at 25°C (77°F), with excursions permitted 15° to 30°C (59° to 86°F).[1] Once opened, DTG 10 mg 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.

DTG PD 5 mg tablets for oral suspension are supplied in bottles of 60 tablets with a child-resistant closure containing a desiccant. Each bottle is packaged with one 30-mL dosing cup and one 10-mL oral dosing

syringe with 1-mL gradations. DTG PD tablets for oral suspension should be stored below 30°C (86°F). Store and dispense the 5-mg tablets in the original bottle, protect from moisture, and keep the bottle tightly closed. Do not remove desiccant.[1] Once opened, DTG PD 5 mg 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.

DTG 25 mg and 50 mg tablets are supplied in bottles of 30 tablets with child-resistant closures. DTG 25 and 50 mg tablets should be stored at 25°C (77°F), with excursions permitted 15° to 30°C (59° to 86°F). Once the original manufacturer's bottle is opened and some tablets are partially dispensed, the remaining 25 or 50 mg 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. The expiration dating of the partially dispensed tablets into a separate container should never exceed the expiration date on the original container.[1]

UNIT DOSE REPACKAGING

There is currently no data on repackaging DTG 25 or 50 mg tablets into unit-dose blister packages.
Do not repackage DTG 10 mg or DTG PD 5 mg tablets for oral suspension into unit-dose blister packages.

SUPPLEMENTAL STABILITY DATA

High and Low Temperature Stability

Studies that evaluated temperature stability excursions for DTG 50 mg and DTG 10 mg tablets showed that stability was maintained at 30°C (86°F) and 75% relative humidity for up to 60 months.[2] The 25 mg dosage form was stable at 30°C (86°F) and 75% relative humidity for up to 48 months. The DTG PD 5 mg tablet for oral suspension was stable at 30°C (86°F) and 75% relative humidity for up to 36 months. Further data indicated that temperatures of 50°C (122°F) at ambient humidity for up to three months and 40°C (104°F) and 75% relative humidity for up to six months found no significant change in stability for all four dosage strengths.

A 28-day freeze-thaw study evaluated DTG 50 mg, 25 mg, and 10 mg 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. Global Data Sheet for dolutegravir, Version 0018, July 21, 2020.
2. Data on File. 2019N420035.