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

Storage, Partial Dispensing and Expiration[1]

ViiV Healthcare cannot recommend the use of *Tivicay* (DTG) tablets or *Tivicay PD* (DTG) tablets for oral suspension when stored outside of the following conditions:

	5 mg	10 mg	25 mg and 50 mg
	• Store and dispense the DTG 5 mg tablets for oral suspension in the original bottle. • Protect from moisture, and keep the bottle tightly closed. • Do not remove desiccant.	• Store and dispense the DTG 10 mg tablets in the original package. • Protect from moisture, and keep the bottle tightly closed. • Do not remove desiccant.	• 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.
	• DTG 5 mg tablets for oral suspension should be stored below 86°F (30°C).	• DTG 10 mg tablets should be stored at 77°F (25°C), with excursions permitted 59°F to 86°F (15°C to 30°C).	• DTG 25 mg and 50 mg tablets should be stored at 77°F (25°C), with excursions permitted 59°F to 86°F (15°C to 30°C).

Expiration Date

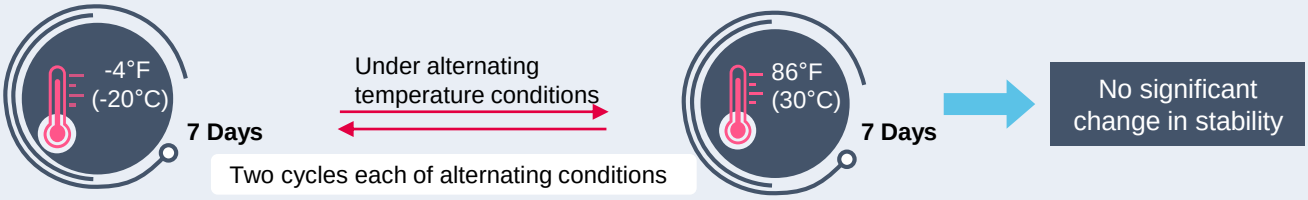
	5 mg and 10 mg	25 mg and 50 mg
	• Once opened, any remaining tablets may be dispensed up to the expiration date that is stamped on the label, as long as the desiccant is present and still intact.	• Once opened, any remaining tablets may be dispensed up until the expiration date that is stamped on the container, when the original bottle is stored in accordance with the recommended temperature range.

Unit Dose Repackaging

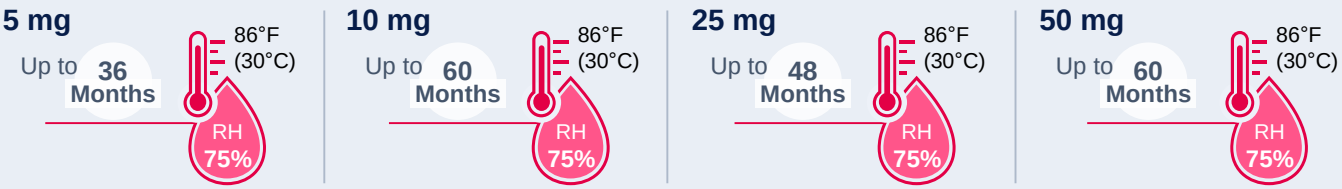
	5 mg and 10 mg	25 mg and 50 mg
	• Do not repackage the 5 mg tablets for oral suspension or the 10 mg tablets into unit-dose blister packages.	• Currently no data is available on repackaging 25 mg or 50 mg tablets into unit-dose blister packages.

Low Temperature Stability[2]

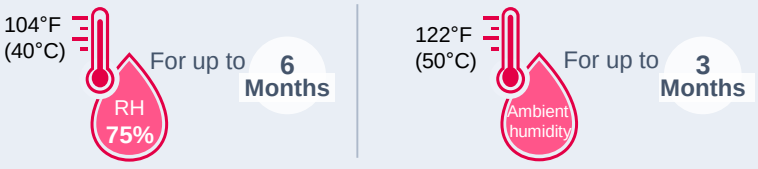
A 28-day freeze-thaw study evaluated DTG **10 mg, 25 mg, and 50 mg:**



High Temperature Stability[2]



No significant change in stability for all four dosage strengths was found at temperature of:



Important safety information is found in the Prescribing Information.

For more information MI Letter Prescribing Information CLICK FOR ViiV US Medical Portal

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

Abbreviations: DTG = dolutegravir, RH = relative humidity.

References: 1. ViiV Healthcare, Global Data Sheet for dolutegravir, Version 0021, August 10, 2022; **2.** Data on File. 2019N420035.