Splitting or Crushing *Tivicay* 10, 25, and 50–mg Tablets or *Tivicay* 5 mg Tablets for Oral Suspension

Summary

- The 10 and 25-mg tablet strengths of *Tivicay* (dolutegravir [DTG]) and/or the *Tivicay* PD tablets for oral suspension may not be approved or available in certain global markets. Please refer to your local label.
- The efficacy and safety of DTG tablets that have been split or crushed prior to administration have not been evaluated.
- To ensure administration of the entire dose of DTG, the tablet(s) should, ideally, be swallowed whole.
- Alternatively, in patients who have difficulty swallowing tablets whole, DTG 10, 25, and 50-mg tablets may be either split into halves followed by immediate ingestion of both halves of the tablet, or crushed and added to a small amount of semi-solid food or liquid, all of which should be consumed immediately.
- Because the tablets are not scored, one DTG 50-mg tablet should not be split to create a 25-mg tablet in situations where both halves would not be administered immediately, including for use by a pediatric patient.
- DTG 5 mg tablets for oral suspension may be swallowed whole or dispersed in drinking water. DTG 5 mg tablets for oral suspension should not be chewed, cut, or crushed.
- Important safety information is found in the enclosed Prescribing Information.

ADMINISTRATION AND CHARACTERISTICS OF DTG

DTG is a film-coated, non-scored, and non-sustained released tablet formulation available in three strengths: 10, 25, and 50-mg.[1] The 10 and 25-mg tablet strengths are intended for use by pediatric patients via weight-based dosing.

The efficacy and safety of DTG tablets that have been split or crushed prior to administration have not been studied. To ensure administration of the entire dose of DTG, the tablet(s) should, ideally, be swallowed whole.[1]

DTG 10, 25, AND 50-MG TABLETS

For patients who cannot or have difficulty swallowing tablets whole, DTG 10, 25, and 50-mg tablets may be split into halves immediately prior to administration.[2] Because the tablets are not scored, one 50-mg tablet should not be split to create a 25-mg tablet in situations where both halves would not be administered immediately, including for use by a pediatric patient. The 10, 25, and 50-mg tablets should only be split to facilitate administration in patients with difficulty swallowing tablets whole.

Additionally, DTG 10, 25, and 50-mg tablets may be carefully crushed and added to a small amount of semi-solid food or liquid, all of which should be consumed immediately.[2] Crushing and mixing DTG 10, 25, and 50-mg tablets as described herein would not be expected to adversely impact the product's pharmaceutical quality, and, therefore, would not be expected to alter the intended clinical effect of DTG. This conclusion

is based on the physicochemical and pharmacokinetic characteristics of the active ingredient, and the in vitro dissolution behavior of the 10, 25, and 50-mg tablets in water, assuming that the patient or caregiver crushes and transfers 100% of the tablet, and the patient ingests the mixture immediately.

DOLUTEGRAVIR 5 MG TABLETS FOR ORAL SUSPENSION

DTG tablets and DTG 5 mg tablets for oral suspension are not bioequivalent and not interchangeable on a milligram-per-milligram basis. Patients changing between DTG and DTG tablets for oral suspension should follow the formulation-specific dosing recommendations.[3]

DTG tablets for oral suspension may be swallowed whole or dispersed in drinking water. The amount of water needed will depend on the number of tablets prescribed. DTG tablets for oral suspension should be fully dispersed in water before swallowing, and the dose should be administered orally within 30 minutes. DTG tablets for oral suspension should not be chewed, cut, or crushed.[3]

Some information contained in this response may not be included in the approved Prescribing Information. 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 0015, October 12, 2018.
2. Data on File. DNG 2016N290532_00.
3. ViiV Healthcare Local Label.