

## Splitting or Crushing Dovato Tablets

### **Summary**

- The efficacy, safety, stability, pharmacokinetic, and physiochemical properties of *Dovato* (dolutegravir/lamivudine [DTG/3TC]) tablets when split or crushed prior to administration have not been evaluated. *Dovato* tablets should be taken orally once daily with or without food. To ensure administration of the entire dose of a *Dovato* tablet, it should be swallowed whole to prevent loss of drug during preparation.
- For patients who cannot swallow a *Dovato* tablet whole, the tablets may, in theory, be split
  into halves immediately prior to administration of both halves.<sup>1</sup> If a physician decides to do
  so, based on his/her clinical judgement, a *Dovato* tablet may, in theory, be crushed and
  added to a small amount of semi-solid food or liquid, all of which should be consumed
  immediately.
- Important safety information and boxed warning(s) can be found in the <u>Prescribing</u>
  <u>Information link</u> and can also be accessed at <u>Our HIV Medicines</u>.

To access additional scientific information related to ViiV Healthcare medicines, visit the ViiV US Medical Portal at viivhcmedinfo.com.



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#### ADMINISTRATION AND CHARACTERISTICS OF DOVATO

Dovato (50 mg DTG/300 mg 3TC) tablets are intended for oral administration, with or without food.<sup>2</sup> Dovato is a film-coated, non-scored, and non-sustained release tablet formulation.<sup>1</sup> Each oval tablet is approximately 18.5 mm x 9.5 mm in size and weighs approximately 918 mg.

#### SPLITTING OR CRUSHING DOVATO TABLETS

The efficacy, safety, stability, pharmacokinetic, and physiochemical properties of *Dovato* tablets that have been split or crushed prior to administration have not been evaluated. To ensure administration of the entire dose of a *Dovato* tablet, it should be swallowed whole to prevent loss of drug during preparation. Therefore, it is not recommended that *Dovato* tablets be split or crushed.

For patients who cannot swallow a *Dovato* tablet whole, the tablets may, in theory, be split into halves immediately prior to administration of both halves. Splitting should only be done to facilitate swallowing of a whole tablet in patients with difficulty swallowing tablets whole. If a physician decides to do so, based on his/her clinical judgement, the tablet may, in theory, be crushed and added to a small amount of semi-solid food or liquid, all of which should be consumed immediately. The conclusions for splitting or crushing *Dovato* tablets are based on the overall stability profile of intact *Dovato* tablets and assume the splitting or crushing process is performed as practically close to dosing as possible with no loss of active ingredients.

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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.



# **REFERENCES**

- Data on File. 2018N389442\_00. ViiV Healthcare Local Label. 1.
- 2.

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