

Splitting or Crushing *Juluca* Tablets

Summary

- *Juluca* (Dolutegravir/rilpivirine, DTG/RPV) tablets are for oral administration with a meal.¹
- The efficacy, safety, pharmacokinetics and physiochemical properties of splitting or crushing DTG/RPV tablets prior to administration have not been evaluated. DTG/RPV tablets should be swallowed whole and taken with a meal to ensure administration of the entire dose.²
- If a physician decides, based on his/her clinical judgment, to split a DTG/RPV tablet in half, it should be split and immediately ingested (both halves) with a meal.² If a physician decides to crush a DTG/RPV tablet for administration, it should be crushed and added to a small amount of semi-solid food or liquid for immediate consumption with a meal. Both circumstances are based on short-term changes to tablet hardness, tablet water content, dissolution rates of DTG and RPV, and RPV free base levels when whole DTG/RPV tablets were exposed to 30°C/75% relative humidity (RH) laboratory conditions, and assume immediate consumption of 100% of the tablet.
- 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 viihcmmedinfo.com.



ADMINISTRATION AND CHARACTERISTICS OF DTG/RPV

DTG/RPV tablets are intended for oral administration, to be taken once daily with a meal.¹ DTG/RPV 50/25 mg is an oval, film-coated, non-scored, and non-sustained release tablet formulation.² Each tablet contains the active ingredients 52.6 mg of DTG sodium (equivalent to 50 mg DTG free acid) and 27.5 mg of RPV hydrochloride (equivalent to 25 mg of RPV free base).¹ The typical oval tablet size is 14.1 mm x 7 mm.²

SPLITTING AND CRUSHING DTG/RPV TABLETS

The efficacy, safety, pharmacokinetics and physiochemical properties of DTG/RPV tablets that have been split prior to administration have not been studied. The tablet should be swallowed whole and taken with a meal.² If a physician decides, based on his/her clinical judgment, to split a DTG/RPV tablet, it should be split into halves immediately prior to administration and taken with a meal, assuming no loss of the active ingredients in the splitting process. This conclusion for immediate consumption is based on the short-term changes to tablet hardness, tablet water content, dissolution rate of DTG and RPV, and RPV free base levels when whole DTG/RPV tablets were exposed to 30°C/75%RH laboratory conditions.

There are no data available to support the efficacy and safety of DTG/RPV tablets that have been crushed prior to administration.² If a physician decides to crush a DTG/RPV tablet for administration, it should be crushed and added to a small amount of semi-solid food or liquid for immediate consumption with a meal (based on the conclusion above). The RPV component of DTG/RPV is known to “stick” or adhere to materials. Therefore, both circumstances assume the patient or caregiver transfers 100% of the tablet, and the patient immediately ingests the mixture.

ADDITIONAL INFORMATION

DTG/RPV was co-developed and is co-promoted by ViiV Healthcare and Janssen Pharmaceuticals. Content in this response relates to data available about the components used together as a complete regimen. If you are seeking medical information specific to the RPV component, please visit <http://www.janssen.com/contact-us> to be directed to global contact information for Janssen Pharmaceuticals.

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Some information contained in this response may not be included in the approved Prescribing Information for this product. 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

1. ViiV Healthcare Local Label.
2. Data on File. 2017N338102.