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GILEAD | Medical Information

Odefsey® (FTC/RPV/TAF) Crushing or Splitting of Tablets

This document is in response to your request for information regarding Odefsey® (emtricitabine/rilpivirine/tenofovir alafenamide [FTC/RPV/TAF]) and the crushing or splitting of tablets.

Some data may be outside of the US FDA-approved prescribing information. In providing this data, Gilead Sciences, Inc. is not making any representation as to its clinical relevance or to the use of any Gilead product(s). For information about the approved conditions of use of any Gilead drug product, please consult the FDA-approved prescribing information.

The full indication, important safety information, and boxed warnings are available at: www.gilead.com/-/media/files/pdfs/medicines/hiv/odefsey/odefsey_pi.

Product Labeling[1]

There is no information in the FTC/RPV/TAF product labeling about the crushing or splitting of FTC/RPV/TAF; therefore, it is not recommended that FTC/RPV/TAF be administered as a crushed or split tablet.

In regard to the individual components of FTC/RPV/TAF, TAF has a solubility of 4.7 mg/mL in water at 20°C, and FTC has a solubility of approximately 112 mg/mL in water at 25°C. RPV hydrochloride is practically insoluble in water over a wide range of pH values.

Available Data on Crushing or Splitting FTC/RPV/TAF Tablets

Gilead Data

Crushing FTC/RPV/TAF tablets and adding to a liquid medium has not been studied and is not recommended. TAF is soluble in water; however, it has a bitter and burnt aromatic flavor profile.[2] Currently, there are no studies evaluating the pharmacokinetics (eg, oral bioavailability) of a crushed FTC/RPV/TAF tablet dispersed in a liquid medium (eg, milk, water, or juice) compared with the pharmacokinetics of a whole tablet.

Similarly, splitting FTC/RPV/TAF tablets has not been studied, and it is not recommended. Currently, there are no studies evaluating the pharmacokinetics of a split FTC/RPV/TAF tablet versus a whole tablet.

Non-Gilead Data

A literature search was conducted in Ovid MEDLINE and Embase databases for studies published up to August 24, 2026, using the search terms Odefsey, emtricitabine, rilpivirine, tenofovir alafenamide, cutting, crushing, splitting tablets, and related search terms. No relevant citations were found.

References

1. Enclosed. Gilead Sciences Inc, ODEFSEY® (emtricitabine, rilpivirine, and tenofovir alafenamide) tablets, for oral use. US Prescribing Information. Foster City, CA.
2. Gilead Sciences Inc. Data on File.

Product Label

For the full indication, important safety information, and boxed warning(s), please refer to the Odefsey US Prescribing Information available at: www.gilead.com/-/media/files/pdfs/medicines/hiv/odefsey/odefsey_pi.

Follow-Up

For any additional questions, please contact Gilead Medical Information at:

☎1-866-MEDI-GSI (1-866-633-4474) or 🖱 www.askgileadmedical.com

Adverse Event Reporting

Please report all adverse events to:

Gilead Global Patient Safety ☎ 1-800-445-3235, option 3 or
🖱 https://www.gilead.com/utility/contact/report-an-adverse-event

FDA MedWatch Program by ☎ 1-800-FDA-1088 or ✉MedWatch, FDA, 5600 Fishers Ln, Rockville, MD 20852 or 🖱 www.accessdata.fda.gov/scripts/medwatch

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