

Complera[®] (FTC/RPV/TDF)

Crushing or Splitting of Tablets

This document is in response to your request for information regarding Complera[®] (emtricitabine/rilpivirine/tenofovir disoproxil fumarate [FTC/RPV/TDF]) 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/complera/complera_pi.

Product Labeling¹

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

While FTC and TDF are soluble in water (FTC and TDF have a solubility of approximately 112 mg/mL and 13.4 mg/mL, respectively, in water at 25°C), RPV hydrochloride is practically insoluble in water over a wide pH range.

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

Gilead Data

Crushing FTC/RPV/TDF tablets and adding into a liquid medium has not been studied and is not recommended. Currently, there are no studies evaluating the pharmacokinetics (eg, oral bioavailability) of a crushed FTC/RPV/TDF tablet dispersed into a liquid medium (eg, milk, water, juice) compared with those of a whole tablet.

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

Non-Gilead Data

A literature search was conducted in Ovid MEDLINE, BIOSIS Previews, and Embase databases for studies published between 1946 and February 4, 2025, using the search terms Complera, rilpivirine, emtricitabine, tenofovir disoproxil fumarate, and cutting, crushing, splitting tablets, and related search terms. No relevant citations were found.

Reference

1. Enclosed. Gilead Sciences Inc, COMPLERA® (emtricitabine, rilpivirine, tenofovir disoproxil fumarate) tablets, for oral use. US Prescribing Information. Foster City, CA.

Product Label

For the full indication, important safety information, and boxed warning(s), please refer to the Complera US Prescribing Information available at:

www.gilead.com/-/media/files/pdfs/medicines/hiv/complera/complera_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

🌐 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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