

Bixlenvo™ (bictegravir/lenacapavir)

Crushing or Splitting of Tablets

This document is in response to your request for information regarding Bixlenvo™ (bictegravir/lenacapavir [BIC/LEN]) 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/BIXLENVO/BIXLENVO_pi

Product Labeling¹

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

In regard to the individual components of BIC/LEN, BIC has a solubility of 0.1 mg/mL in water at 20°C and LEN is practically insoluble in water.

Available Data on Crushing or Splitting BIC/LEN

Gilead Data

Crushing BIC/LEN 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 BIC/LEN tablet dispersed into a liquid medium (eg, milk, water, juice) compared to a whole tablet.

Similarly, splitting BIC/LEN tablets has not been studied and it is not recommended. Currently, there is no study evaluating the pharmacokinetics of a split tablet versus a whole tablet.

Non-Gilead Data

A literature search was conducted in Ovid MEDLINE and Embase databases for studies published between 1946 and August 10, 2026 using search terms that included bictegravir, lenacapavir, cutting, crushing, splitting tablets and other related search terms. No relevant citations were identified.

References

1. Enclosed, Gilead Sciences Inc. BIXLENVO™ (bictegravir and lenacapavir) tablets, for oral use. U.S. Prescribing Information. Foster City, CA.

Product Label

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

www.gilead.com/-/media/files/pdfs/medicines/hiv/BIXLENVO/BIXLENVO_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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