GILEAD | Medical Information

Sunlenca® (lenacapavir) Crushing or Splitting of Tablets

This document is in response to your request for information regarding Sunlenca® (lenacapavir [LEN]) and 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/sunlenca/sunlenca_pi.

Product Labeling[1]

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

LEN is practically insoluble in water.

Available Data on Crushing and Splitting of Tablets

Gilead Data

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

Similarly, splitting 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 November 7, 2025, using the search terms of Sunlenca, lenacapavir, cutting, crushing, splitting tablets and related search terms. No relevant citations were found.

Reference

1. Enclosed, Gilead Sciences Inc. SUNLENCA® (lenacapavir) tablets, for oral use. SUNLENCA® (lenacapavir) injection, for subcutaneous 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 Sunlenca US Prescribing Information available at: www.gilead.com/-/media/files/pdfs/medicines/hiv/sunlenca/sunlenca_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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