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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.

Administration via nasogastric tube[2]

The administration of crushed LEN tablets via nasogastric (NG) tube has not been evaluated by any regulatory authority.

There are currently no known published clinical data or patient outcomes regarding the administration of LEN tablets via NG tube: the safety and efficacy of administering LEN via NG tube have not been established. The effect of crushing LEN tablets on the absorption profile of LEN has not been studied.

In vitro feasibility study

An in vitro feasibility study of LEN tablet administration via NG tube conducted at Gilead Sciences demonstrated only that the physical passage of a LEN tablet suspension through

NG tubes of various sizes is possible under laboratory conditions. The information provided is not intended to serve as a clinical recommendation or guidance for patient care.

The study evaluated if a LEN (GS-6207) tablet, when suspended in water, can be administered through Avanos nasogastric tubes of sizes 5 Fr, 8 Fr, and 12 Fr. (Fr is an abbreviation for French gauge [French size], which is a unit of measurement used to describe the outer diameter of medical tubes, such as NG tubes; 1 Fr is equivalent to a diameter of 0.33 mm.)

One 300 mg LEN tablet was dispersed in 120 mL deionized water and stirred for up to 18 minutes. The resulting suspension was passed through NG tubes of the specified sizes using a syringe. The suspension passed through all tube sizes, with no pressure build-up or obstruction. Additional rinsing and passage of remaining material passed through the tube without incident.

This in vitro feasibility study found that LEN tablets can be suspended in water and physically administered through NG tubes of 5 Fr, 8 Fr, and 12 Fr sizes without incident.

Healthcare professionals should use their clinical judgment and refer to approved prescribing information and institutional protocols when considering alternative administration methods.

Non-Gilead Data

A literature search was conducted in Ovid MEDLINE and Embase databases for studies published between 1946 and October 23, 2026, 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.
2. Gilead Sciences Inc. Data on File.

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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