

Sunlenca® (Ienacapavir) Coadministration with Enoxaparin

This document is in response to your request for information regarding Sunlenca® (lenacapavir [LEN]) and coadministration with enoxaparin.

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: http://www.gilead.com/-/media/files/pdfs/medicines/hiv/sunlenca/sunlenca_pi.

PK DDI Evaluation

This interaction has not been studied between LEN and enoxaparin. Based on the PK profile of LEN and enoxaparin, a PK interaction would not be predicted.^{1,2} For more information about enoxaparin, please refer to its product labeling.²

LEN PK^{1,3}

DDI Mechanism		LEN
Drug Transporters	OCT2	NA
	MATE1	NA
	P-gp	Substrate ^a Weak Inhibitor
	BCRP	Weak Inhibitor
	OATP1B1	NA
	OATP1B3	NA
Drug Metabolizing Enzymes	CYP3A	Substrate ^{a,b} Moderate inhibitor
	UGT1A1	Substratea

^aCombined P-gp, UGT1A1, and strong CYP3A inhibitors may significantly increase plasma concentrations of LEN. Concomitant administration of LEN with these inhibitors is not recommended.

^bDrugs that are strong or moderate inducers of CYP3A may significantly decrease plasma concentrations of LEN, which may result in loss of therapeutic effect of LEN and development of resistance. Concomitant administration of LEN with strong CYP3A inducers during LEN treatment is contraindicated. Concomitant administration of LEN with moderate CYP3A inducers during LEN treatment is not recommended.

Relevant LEN Label Information¹

There is no information in the LEN product labeling about the coadministration of LEN and enoxaparin.

Gilead Sciences, Inc. is providing this document to you, a US Healthcare Professional, in response to your unsolicited request for medical information.

Available Data

There are no Gilead studies evaluating the coadministration of LEN and enoxaparin.

Additionally, a literature search was conducted in Ovid MEDLINE and Embase databases for studies published between 1946 and April 11, 2025 using search terms that included Sunlenca, lenacapavir, enoxaparin, and related search terms. No relevant citations were found.

References

- 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. Sanofi-Aventis U.S. LLC, Lovenox (enoxaparin sodium) injection, for subcutaneous and intravenous use. U.S. Prescribing Information. Bridgewater, NJ.
- Lutz J. CLINICAL EVALUATION OF DRUG INTERACTIONS WITH ORAL LENACAPAVIR AND PROBE DRUGS [Presentation]. Paper presented at: Conference on Retroviruses and Opportunistic Infections (CROI); March 6-10, 2021; Virtual.

Abbreviations

BCRP=breast cancer resistance protein DDI=drug-drug interaction LEN=lenacapavir MATE=multidrug and toxin extrusion protein NA=not applicable OATP=organic anion transporting polypeptide OCT=organic cation transporter P-gp=P-glycoprotein PK=pharmacokinetic(s) UGT=uridine 5'-diphosphoglucuronosyltransferase

Product Label

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

Follow-Up

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

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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