GILEAD | Medical Information

Sunlenca® (lenacapavir) Coadministration with Phenobarbital

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

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 phenobarbital. Based on the PK profile of LEN and phenobarbital, a PK interaction would be predicted. CYP3A inducers, like phenobarbital, may decrease LEN plasma concentrations which may result in loss of therapeutic effect and development of resistance.[1,2] Coadministration is not recommended. Alternative anticonvulsants should be considered.[1] For more information about phenobarbital, 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	Substrate[a]

[a]Combined P-gp, UGT1A1, and strong CYP3A inhibitors may significantly increase plasma concentrations of LEN. Concomitant administration of LEN with these inhibitors is not recommended.
[b]Drugs 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 Information[1]

Concomitant administration of LEN with phenobarbital may result in loss of therapeutic effect and development of resistance. Concomitant administration of LEN with phenobarbital is not recommended. Consider use of alternative anticonvulsants.

Available Data

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

A literature search was conducted in Ovid MEDLINE, BIOSIS Previews, and Embase databases for studies published between 1946 and December 23, 2024 using search terms that included Sunlenca, lenacapavir, phenobarbital, 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. Sun PharmaceuticalIndustries, Inc., SEZABYTM™ (phenobarbital sodium) for injection, for intravenous use, CIV. U.S. Prescribing Information. Cranbury, NJ
3. 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'-diphospho-glucuronosyltransferase

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:

☎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
🖱 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

Data Privacy

The Medical Information service at Gilead Sciences may collect, store and use your personal information to provide a response to your medical request. We may share your information with other Gilead Sciences colleagues to ensure that your request is addressed appropriately. If you report an adverse event or concern about the quality of a Gilead or Kite product, we will need to use the information you have given us in order to meet our regulatory requirements in relation to the safety of our medicines.

It may be necessary for us to share your information with Gilead's affiliates, business partners, service providers and regulatory authorities located in countries besides your own. Gilead Sciences has implemented measures to protect the personal information you provide. Please see the Gilead Privacy Statement (www.gilead.com/privacy-statements) for more information about how Gilead handles your personal information and your rights. If you have any further questions about the use of your personal information, please contact privacy@gilead.com.