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GILEAD | Medical Information

# Bixlenvo™ (bictegravir/lenacapavir) Use in Pediatric and Adolescent Individuals

This document is in response to your request for information regarding the use of Bixlenvo™ (bictegravir/lenacapavir [BIC/LEN]) in pediatric and adolescent individuals.

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 Labeling[1]

The safety and effectiveness of BIC/LEN have not been established in patients less than 18 years of age.

## Clinical Data

Currently there is no data to address this inquiry. The ARTISTRY-1 and ARTISTRY-2 studies enrolled participants who were aged 18 years or older.[2,3]

GS-US-621-6463 (NCT06532656) is an ongoing phase 2/3 study evaluating the safety, tolerability and PK of BIC/LEN in virologically suppressed children and adolescents with HIV-1 on a stable and complex ARV regimen. The study will also assess the safe loading dose of LEN in this population.[4]

## Literature search

A literature search was conducted in Ovid MEDLINE and Embase databases for studies published between 1946 and August 10th 2026 using search terms that included bictegravir, lenacapavir, child, pediatric, adolescent 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.
2. ClinicalTrials.gov. Study to Compare Bictegravir/Lenacapavir Versus Current Therapy in People With HIV-1 Who Are Successfully Treated With a Complicated Regimen (ARTISTRY-1). Available at: https://classic.clinicaltrials.gov/ct2/show/NCT05502341

3. ClinicalTrials.gov. Study to Compare Bictegravir/ Lenacapavir Versus Current Therapy in PeopleWith HIV-1 Who Are Successfully Treated With Biktarvy (ARTISTRY-2). Available at: https://clinicaltrials.gov/study/NCT06333808#participation-criteria.
4. ClinicalTrials.gov. Study of Bictegravir/ Lenacapavir in Children and Adolescents With HIV-1. Available at: https://clinicaltrials.gov/study/NCT06532656.

## Abbreviations

ARV=antiretroviral
BIC=bictegravir
LEN=lenacapavir
PK=pharmacokinetics

## 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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