



Bixlenvo™ (bictegravir/lenacapavir)

Use in People with HIV-2

This document is in response to your request for information regarding Bixlenvo™ (bictegravir/lenacapavir [BIC/LEN]) in people with HIV-2.

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The full indication, important safety information, and boxed warnings are available at: www.gilead.com/-/media/files/pdfs/medicines/hiv/BIXLENVO/BIXLENVO_pi.

Product Labeling¹

Indications and Usage

BIC/LEN is indicated as a complete regimen for the treatment of HIV-1 in adults to replace the current antiretroviral regimen in those who are virologically suppressed (HIV-1 RNA less than 50 copies per mL) on a stable antiretroviral regimen with no known or suspected resistance to the individual components of BIC/LEN.

Microbiology

The combination of BIC and LEN was not antagonistic with respect to antiviral activity in cell culture.

Bictegravir: The antiviral activity of BIC against laboratory and clinical isolates of HIV-1 was assessed in lymphoblastoid cell lines, PBMCs, primary monocyte/macrophage cells, and CD4+ T-lymphocytes. In MT-4 cells (human lymphoblastoid T-cell line) acutely infected with HIV-1 IIIB, the mean 50% effective concentration (EC₅₀) was 2.4±0.4 nM, and the protein-adjusted EC₉₅ value was 361 nM (0.162 micrograms per mL).

BIC displayed antiviral activity in activated PBMCs against clinical isolates of HIV-1 representing groups M, N, and O, including subtypes A, B, C, D, E, F, and G, with a median EC₅₀ value of 0.55 nM (range <0.05 to 1.71 nM). The EC₅₀ value against a single HIV-2 isolate was 1.1 nM.

Lenacapavir: LEN has antiviral activity that is specific to human immunodeficiency virus (HIV-1 and HIV-2). The antiviral activity of LEN against laboratory and clinical isolates of HIV-1 was assessed in T-lymphoblastoid cell lines, PBMCs, primary monocyte/macrophage cells, and CD4+ T-lymphocytes with EC₅₀ values ranging from 30 to 190 pM.

LEN displayed antiviral activity in cell culture against all HIV-1 groups (M, N, O), including subtypes A, A1, AE, AG, B, BF, C, D, E, F, F1, G, H with EC₅₀ values ranging from 20 and 160 pM. The median EC₅₀ value for subtype B isolates (n=8) was 40 pM.

LEN was 15- to 25-fold less active against HIV-2 isolates relative to HIV-1.

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, HIV-2, human immunodeficiency virus-2 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.

Abbreviations

BIC=bictegravir

LEN=lenacapavir

PMBC=peripheral blood
mononuclear cell

Product Label

For the full indication, important safety information, and boxed warning(s), please refer to the Bixlenvo US Prescribing Information available at:

http://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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