

BIXLENVO™
bictegravir 75mg / lenacapavir 50mg tablets

NOW APPROVED

A new, purposely paired combination of medicines working together in the smallest complete HIV pill available.*

*After 2-day starter doses.

For people living with HIV who are undetectable,[†] and are considering switching from either **a multi-pill HIV regimen** or a **single-tablet regimen**, and whose healthcare provider determines they meet certain requirements.

Talk to a healthcare provider to see if BIXLENVO™ is right for you.

[†]Undetectable means that there is so little virus in the blood that a lab test cannot measure it (less than 50 copies/mL).

What is BIXLENVO?

BIXLENVO is a prescription medicine that is used to treat HIV-1 in adults to replace their current HIV-1 medicines when their healthcare provider determines that they meet certain requirements.

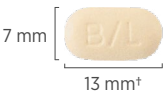
BIXLENVO does not cure HIV-1 or AIDS. HIV-1 is the virus that causes AIDS.

Please click to see Important Facts about BIXLENVO on page 6.

About BIXLENVO™ and how to take it

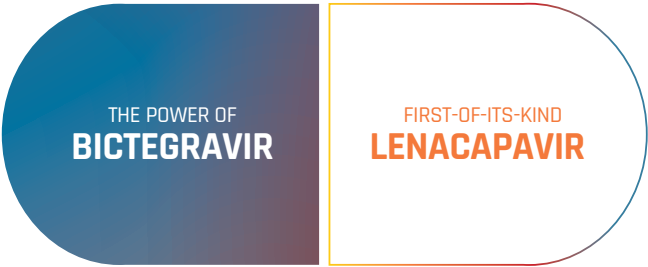
BIXLENVO is the smallest* complete once-daily pill for HIV treatment.

*After 2-day starter doses.



BIXLENVO is taken by mouth, with or without food.

†Pill image not actual size.



It combines the power of bictegrovir with first-of-its-kind lenacapavir.

Important Safety Information

Who should not take BIXLENVO?

- **Do not take BIXLENVO if you** take dofetilide or certain other medications called strong CYP3A inducers. Ask your healthcare provider if you are not sure.

What are the possible side effects of BIXLENVO?

- **The most common side effects** of BIXLENVO in clinical studies were headache (4%), nausea (3%), and diarrhea (2%). These are not all the possible side effects of BIXLENVO. Call your doctor for medical advice about side effects.

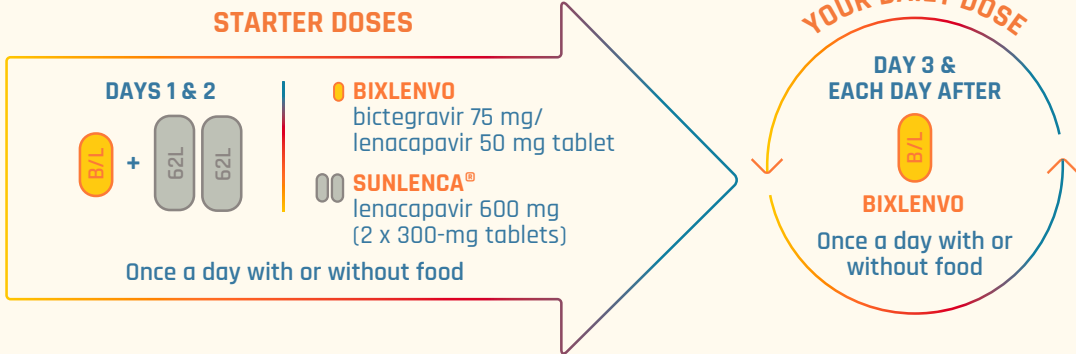


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Getting started with BIXLENVO:

- 1** You will receive **2 bottles of pills** when you start BIXLENVO. One bottle has BIXLENVO and the other has SUNLENCA®. Together, these are your starter doses.
- 2** For the **first 2 days only**, you will need to take one BIXLENVO tablet and two SUNLENCA tablets together, by mouth, with or without food. It's important to take BIXLENVO with SUNLENCA on the first 2 days. Talk to your healthcare provider if you have questions.
- 3** For **day 3 and each day after**, you will only need to take BIXLENVO once-daily, by mouth, with or without food.

BIXLENVO dosing: Let's break it down



Why are the starter doses important?

The starter doses help quickly raise levels of lenacapavir, a medicine in BIXLENVO, so there is enough medicine in your body for it to begin working. That's why it's very important to take BIXLENVO with SUNLENCA during the first 2 days only. It is also important not to take Day 1 and 2 of SUNLENCA on the same day. Contact your healthcare provider if you have questions about taking BIXLENVO.



What happens if you miss a dose of BIXLENVO?

If you miss a dose of BIXLENVO, take it as soon as possible. If more than 7 days have passed since your last dose of BIXLENVO, contact your healthcare provider right away as your healthcare provider will need to determine how to continue your HIV treatment.

BIXLENVO™ was evaluated across a diverse range of people in 2 clinical studies

ARTISTRY-1	ARTISTRY-2
Studied people on a complex multi-pill regimen* who switched to BIXLENVO vs. those who stayed on their current treatment	Studied people on a single-tablet regimen† who switched to BIXLENVO vs. those who stayed on their current treatment
 Typical age of people was 60 years old	 Typical age of people was 49 years old
 Typical amount of time on HIV treatment was 28.3 years	 Typical amount of time on HIV treatment was 12 years
 More than half had 2 or more additional health conditions	 About 1 in 3 people had 2 or more additional health conditions

*A complex regimen in ARTISTRY-1 involved multiple pills, multiple daily doses, injectable and oral medicines used together, or certain combinations of HIV medicines.

†The single-tablet regimen in ARTISTRY-2 was BIKTARVY® (bictegravir, emtricitabine, tenofovir alafenamide).

Important Safety Information (cont'd)

What should I tell my healthcare provider before taking BIXLENVO?

- **All your health problems**, including if you have hepatitis B virus (HBV).
- **If you are pregnant** or plan to become pregnant. Tell your healthcare provider if you become pregnant during treatment with BIXLENVO.



Please click to see [Important Facts about BIXLENVO on page 6.](#)

The ARTISTRY-1 and ARTISTRY-2 studies included more than 1,000 people combined, including those with more complex HIV treatment histories.‡



Both studies included people who were undetectable§ for at least 6 months before starting and varied in age, gender, and background.



Some people switched to BIXLENVO (371 people in ARTISTRY-1, 383 people in ARTISTRY-2) and some continued their current treatment (186 people in ARTISTRY-1, 191 people in ARTISTRY-2). A goal of the studies was to see whether people remained undetectable after being on treatment for a year with BIXLENVO compared to those on a complex multi-tablet regimen or a leading single-tablet regimen.



At 1 year, most people who switched from their current treatment to BIXLENVO and took their treatment every day stayed undetectable (96% compared to 94% undetectable on a complex multi-tablet regimen in ARTISTRY-1, 93% compared to 91% undetectable on a leading single-tablet regimen in ARTISTRY-2).

‡Some people within both clinical trials had a history of resistance.

§Undetectable means that there is so little virus in the blood that a lab test cannot measure it (less than 50 copies/mL).

Common side effects of BIXLENVO:

In 2 clinical trials, the most common side effects in ≥2% of people taking BIXLENVO at 1 year were headache, nausea, and diarrhea.

In both studies, 2% of people stopped taking BIXLENVO due to side effects compared to 1% of people on multi-pill regimens and 2% of people taking a single-tablet regimen.

Important Safety Information (cont'd)

- **If you are breastfeeding** (nursing) or plan to breastfeed. BIXLENVO passes to your baby in your breast milk. Talk to your healthcare provider about the risks to your baby from breastfeeding during treatment with BIXLENVO.
- **All the medicines you take**, including prescription and over-the-counter medicines, vitamins, and herbal supplements, including St. John's Wort. BIXLENVO and other medicines may affect each other. Keep a list of all your medicines and show it to your healthcare provider and pharmacist and ask if it is safe to take BIXLENVO with all of your other medicines. Do not start a new medicine without telling your healthcare provider.

Important Safety Information

What is BIXLENVO™?

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Important Safety Information

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You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

Notes



Please click to see Important Facts about BIXLENVO on page 6.



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Information about paying for BIXLENVO™

Once you and your healthcare provider determine that BIXLENVO may be right for you, **Gilead's Advancing Access® Program** may be able to help, regardless of your insurance.



If eligible, you may be able to pay **as little as \$0** for your co-pay.*



Get help identifying potential sources of financial support if **you have government insurance**.



Get help identifying potential sources of financial support **if you are uninsured**.

*For commercially insured eligible patients only. Restrictions apply. Subject to change. See full terms and conditions at [GileadAdvancingAccess.com](https://www.gileadadvancingaccess.com)

Learn more and enroll at [GileadAdvancingAccess.com](https://www.gileadadvancingaccess.com) or call 1-800-226-2056 (Monday–Friday, 9 AM to 8 PM ET)

You can also leave a confidential message any time and day of the week. If a voicemail is left after hours, an Advancing Access Program specialist will return your call the next business day. **OR** enroll at [GileadAdvancingAccess.com](https://www.gileadadvancingaccess.com) for 24/7 support online.

Learn more about getting BIXLENVO at [BIXLENVO.com](https://www.bixlenvo.com)

Please click to see Important Facts about BIXLENVO on page 6.

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(bix-LEN-vo)

ABOUT BIXLENVO

BIXLENVO is a prescription medicine used to treat HIV-1 in adults to replace their current HIV-1 medicines when their healthcare provider determines that they meet certain requirements.

BIXLENVO does not cure HIV-1 or AIDS. HIV-1 is the virus that causes AIDS.

Do not take BIXLENVO if you take dofetilide or certain other medications called strong CYP3A inducers. Ask your healthcare provider if you are not sure.

BEFORE TAKING BIXLENVO

Tell your healthcare provider all your medical conditions, including if you:

- Have hepatitis B virus (HBV).
- Are pregnant or plan to become pregnant.
- Are breastfeeding or plan to breastfeed. Talk to your healthcare provider about the risks to your baby from breastfeeding during treatment with BIXLENVO.

Tell your healthcare provider about all the medicines you take:

- Keep a list of all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements, including St. John's wort, and show it to your healthcare provider and pharmacist.
- Ask your healthcare provider or pharmacist about medicines that interact with BIXLENVO.
- Do not start a new medicine without telling your healthcare provider.

POSSIBLE SIDE EFFECTS OF BIXLENVO

The most common side effects of BIXLENVO in clinical studies were headache (4%), nausea (3%), and diarrhea (2%). These are not all the possible side effects of BIXLENVO. Call your doctor for medical advice about side effects.

IMPORTANT FACTS

This is only a brief summary of important information about BIXLENVO™ and does not replace talking to your healthcare provider about your condition and your treatment

HOW TO TAKE BIXLENVO

- Your treatment includes BIXLENVO tablets and, **for the first two days only**, another separate medicine called SUNLENCA® tablets.
- Take BIXLENVO and SUNLENCA tablets by mouth, with or without food.
Your dosing schedule will start as follows:
 - On **Day 1**, take 1 BIXLENVO tablet and 2 SUNLENCA tablets.
 - On **Day 2**, take 1 BIXLENVO tablet and 2 SUNLENCA tablets.
 - **It is very important that you take BIXLENVO with SUNLENCA on these first two days.** Contact your healthcare provider if you have questions.

Your dosing schedule will then continue as follows:

- On **Day 3 and each day after**, take 1 BIXLENVO tablet each day.
- If you miss a dose of BIXLENVO or SUNLENCA on Day 1 or Day 2, take it as soon as possible. Do not take Day 1 and Day 2 doses of SUNLENCA on the same day.
- If you miss a dose of BIXLENVO on Day 3 and each day after, take it as soon as possible. If more than 7 days have passed since your last dose of BIXLENVO, contact your healthcare provider as your healthcare provider will need to determine how to continue your HIV-1 treatment.

GET MORE INFORMATION

- This is only a brief summary of important information about BIXLENVO. Talk to your healthcare provider or pharmacist to learn more.
- Go to BIXLENVO.com or call 1-800-GILEAD-5.
- If you need help paying for your medicine, visit BIXLENVO.com for program information.



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