

PATIENT INFORMATION
BIXLENVO™ (bix-LEN-vo)
(bictegravir and lenacapavir)
tablets, for oral use

What is BIXLENVO?

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

HIV-1 is the virus that causes Acquired Immune Deficiency Syndrome (AIDS).

It is not known if BIXLENVO is safe and effective in children.

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

Before taking BIXLENVO, tell your healthcare provider about all your medical conditions, including if you:

- have hepatitis B virus (HBV).
- are pregnant or plan to become pregnant.
 - Tell your healthcare provider if you become pregnant during treatment with BIXLENVO.
 - **Pregnancy Exposure Registry:** There is a pregnancy exposure registry for women who take BIXLENVO during pregnancy. The purpose of this registry is to collect information about the health of you and your baby. Talk with your healthcare provider about how you can take part in this registry.
- are breastfeeding or plan to breastfeed. BIXLENVO passes to your baby in your breastmilk. Talk with your healthcare provider about the following risks to your baby from breastfeeding during treatment with BIXLENVO:
 - The HIV-1 virus may pass to your baby if your baby does not have HIV-1.
 - The HIV-1 virus may become harder to treat if your baby has HIV-1.
 - Your baby may get side effects from BIXLENVO.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements, including St. John's wort. Some medicines may interact with BIXLENVO. Keep a list of your medicines and show it to your healthcare provider and pharmacist when you get a new medicine.

- You can ask your healthcare provider or pharmacist for a list of medicines that interact with BIXLENVO.
- **Do not start a new medicine without telling your healthcare provider.** Your healthcare provider can tell you if it is safe to take BIXLENVO with other medicines.

How should I take BIXLENVO?

- Take BIXLENVO exactly as your healthcare provider tells you to take it.
- Your treatment includes BIXLENVO tablets and, **for the first 2 days only**, another 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 2 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 take antacids that contain aluminum or magnesium, take BIXLENVO at least 2 hours before or 6 hours after you take these antacids.
- If you take supplements or antacids that contain iron or calcium, take BIXLENVO with food at the same time that you take these supplements or antacids.
- If you are pregnant and take supplements or antacids that contain aluminum, magnesium, iron or calcium, talk to your healthcare provider about how to take BIXLENVO along with these supplements or antacids.
- 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.
- If you take too much BIXLENVO, call your healthcare provider or go to the nearest hospital emergency room right away.
- When your BIXLENVO supply starts to run low, get more from your healthcare provider or pharmacy. This is very important because the amount of virus in your blood may increase if the medicine is stopped for even a short time. The virus may develop resistance to BIXLENVO and become harder to treat.

What are the possible side effects of BIXLENVO?

The most common side effects of BIXLENVO are headache, nausea, and diarrhea.

These are not all the possible side effects of BIXLENVO.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store BIXLENVO?

- Store BIXLENVO tablets at room temperature between 68 °F to 77 °F (20 °C to 25 °C).
- BIXLENVO bottle contains a desiccant canister to help keep your medicine dry (protect it from moisture). Keep the desiccant canister in the bottle. **Do not eat the desiccant canister.**
- Keep BIXLENVO tablets in their original bottle.
- Keep the bottle tightly closed.
- BIXLENVO bottle has a child resistant cap closure.

Keep BIXLENVO and all medicines out of the reach of children.

General information about the safe and effective use of BIXLENVO.

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use BIXLENVO for a condition for which it was not prescribed. Do not give BIXLENVO to other people, even if they have the same symptoms that you have. It may harm them. You can ask your pharmacist or healthcare provider for information about BIXLENVO that is written for health professionals.

What are the ingredients in BIXLENVO?

Active ingredients: bictegrovir sodium and lenacapavir sodium

Inactive ingredients: copovidone, croscarmellose sodium, magnesium stearate, mannitol, microcrystalline cellulose, and poloxamer 407. The tablets are film-coated with a coating material containing iron oxide yellow, polyethylene glycol, polyvinyl alcohol, talc, and titanium dioxide.

Manufactured for and distributed by: Gilead Sciences, Inc. Foster City, CA 94404

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For more information, call 1-800-445-3235 or go to www.BIXLENVO.com.

This Patient Information has been approved by the U.S. Food and Drug Administration.

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