



tenofovir alafenamide)

How should I store BIKTARVY?

This information is provided in response to your question. It is not treatment advice on how to use BIKTARVY. Please discuss this question and others you have about your medical condition or treatment with your healthcare provider.

Download the BIKTARVY Patient Information for more details, including approved use(s) and important warnings: https://www.gilead.com/-/media/files/pdfs/medicines/hiv/biktarvy/biktarvy_patient_pi.pdf

The short answer

Bottles

- BIKTARVY bottles should be stored below 86°F (30°C).
- Keep the bottles tightly closed with the desiccant (a substance that absorbs moisture) inside the bottle to protect it from moisture.
- BIKTARVY should remain in its original container.

Blister packs

- BIKTARVY blister packs should be stored at room temperature 68°F to 77°F (20– 25 °C).
- BIKTARVY should remain in its original blister pack.

Storing BIKTARVY in conditions different from those described in the **BIKTARVY Patient Information** may affect how well BIKTARVY works. If you have additional questions regarding BIKTARVY storage information, please contact your healthcare provider or pharmacist.

What is the most important information I should know about BIKTARVY?

Some medications have important warnings that are designed to alert you of serious or life-threatening risks that come with taking the medication.

BIKTARVY has an important warning for: Worsening of hepatitis B virus (HBV).

Your healthcare provider will test you for HBV before or when you start treatment with BIKTARVY. If you have HBV and take BIKTARVY, your HBV may get worse (flare-up) if you stop taking BIKTARVY. A "flare-up" is when your HBV suddenly returns in a worse way than before.

- Do not run out of BIKTARVY. Refill your prescription or talk to your healthcare provider before your BIKTARVY is all gone.
- Do not stop taking BIKTARVY without first talking to your healthcare provider.
- If you stop taking BIKTARVY, your healthcare provider will need to check your health often and do blood tests regularly for several months to check your liver, and may give you a medicine to treat hepatitis B. Tell your healthcare provider about any new or unusual symptoms you may have after you stop taking BIKTARVY.

Who is BIKTARVY for?

BIKTARVY is a prescription medicine that is used without other human immunodeficiency virus-1 (HIV-1) medicines to treat HIV-1 in adults and children who weigh at least 31 pounds (14 kg):

- who have not received HIV-1 medicines in the past, or
- who have received HIV-1 medicines in the past, or to replace their current HIV-1 medicines, and whose 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 BIKTARVY is safe and effective in children who weigh less than 31 pounds (14 kg).

How is BIKTARVY supplied?

BIKTARVY tablets are available in bottles and blister packs.

Bottle

Each bottle contains 30 tablets, a silica gel desiccant (a substance that absorbs moisture), polyester coil (a filler, which looks like cotton, commonly used in packaging of medicines), and is closed with a child-resistant closure. Do not remove the desiccant packet. Keep the bottle tightly closed.

Blister Pack

Each blister pack contains 30 tablets (4 strips each containing 7 tablets and 1 strip containing 2 tablets).

Blister packs are sealed with a child-resistant foil. Each blister cavity contains a tablet and a special desiccant film to keep the tablet dry. The film is attached to the top of the foil.

How should I store BIKTARVY bottles?

BIKTARVY bottles should be stored **below 86°F (30°C)**. Keep the bottles **tightly closed** and **protect from moisture**.

BIKTARVY contains a desiccant packet to help protect it from moisture. **Keep the desiccant packet in the bottle. Do not eat the desiccant packet.**

BIKTARVY should remain in its **original** bottle.

BIKTARVY comes in a child-resistant package. **Keep BIKTARVY and all medicines out of reach of children.**

How should I store BIKTARVY blister packs?

BIKTARVY blister packs should be stored at room temperature 68°F to 77°F (20–25 °C).

BIKTARVY should remain in its original blister pack.

Gilead Sciences, Inc. is providing this letter in response to your unsolicited request for medical information. It is not promotional. It is intended for a US audience 18 years or older.

BIKTARVY comes in a child-resistant package. **Keep BIKTARVY and all medicines** out of reach of children.

Glossary

Desiccant: a substance that absorbs moisture

Polyester coil: a filler, which looks like cotton, commonly used in packaging of medicines.

References

1. Enclosed, Gilead Sciences, Inc., BIKTARVY® (bictegravir, emtricitabine, and tenofovir alafenamide) tablets, for oral use. U.S. Prescribing Information. Foster City, CA.

More information about BIKTARVY

If you would like more detailed information about BIKTARVY, please visit: https://www.gilead.com/-/media/files/pdfs/medicines/hiv/biktarvy/biktarvy_pi.pdf

This is the US FDA-approved Prescribing Information, including the Patient Labeling, for BIKTARVY. It will tell you about the uses, warnings, and other important safety information about BIKTARVY.

Important note

Gilead Sciences, Inc. is providing this letter in response to your unsolicited request for medical information. Some of the information included in this letter may not be covered in the US FDA-approved Prescribing Information for BIKTARVY. Gilead Sciences, Inc. does not intend this letter to be used as medical advice and does not promote use of BIKTARVY in a way that has not been approved by the FDA. Please discuss this question and others you may have about your medical condition or treatment with your healthcare provider.

Follow-Up

For any additional questions, please contact Gilead Medical Information at:

1-866-MEDI-GSI (1-866-633-4474) or https://www.patient.askgileadmedical.com/

Reporting side effects

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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