



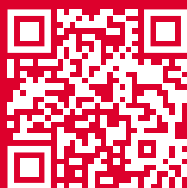
HIV treatment with

BIKTARVY®





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You can find all of the important information about BIKTARVY® on **www.meine-hiv-therapie.de**. Simply scan the QR code and log in with the PZN number (on the BIKTARVY® pack).

BIKTARVY®: composition and mode of action

BIKTARVY® is a single tablet to treat infection with human immunodeficiency virus 1 (HIV-1) in adults, adolescents, and children from the age of 2 with a body weight of at least 14 kg.

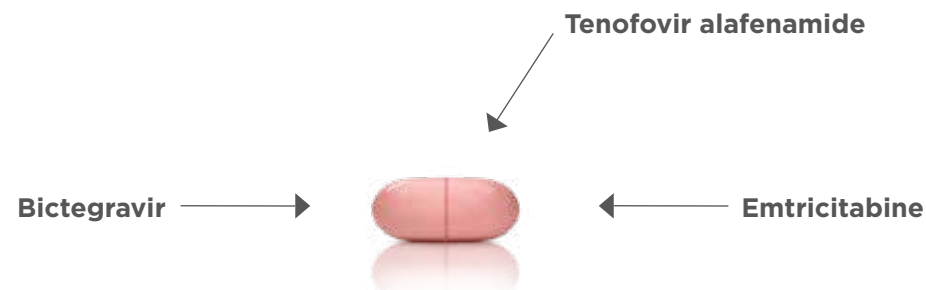
Three active substances are combined in BIKTARVY®. They reduce the quantity of virus in the body, ideally to below the limit of detection (HIV-1 RNA < 50 copies/ml). The immune system can then recover and the risk of secondary diseases is decreased.

BIKTARVY® contains three active substances that come from two complementary active substance classes. The combination reduces the viral load by inhibiting the enzymes needed for the HIV virus to multiply.



There are two doses of BIKTARVY® tablets that the attending physician will prescribe, depending on the patient's age and body weight.

- Adults, adolescents and children who weigh at least 25 kg: **BIKTARVY® 50 mg/200 mg/25 mg film-coated tablets**
- For children from the age of 2 who weigh at least 14 kg but less than 25 kg: **BIKTARVY® 30 mg/120 mg/15 mg film-coated tablets**





Use: taking

BIKTARVY®

Regularity is critical to the success of treatment with BIKTARVY®. It's important to take BIKTARVY® consistently.

- ▶ Adults, adolescents and children with a body weight of at least 25 kg take **one 50 mg/200 mg/25 mg tablet once daily.**
- ▶ Children from the age of 2 with a body weight of at least 14 kg but less than 25 kg take **one 30 mg/120 mg/15 mg tablet once daily.**

Taking and storing the tablets:

- ▶ **One tablet once daily (do not chew or crush*)**
- ▶ **Flexible time of day, does not need to be taken with a meal**
- ▶ **Store in the original package and always well sealed**
- ▶ **Store protected from moisture**

 **1x daily**

The tablets should always be taken following a consultation with the attending physician.

***Splitting the BIKTARVY® tablet**

Chewing or crushing the film-coated tablets is not recommended due to the bitter taste. If it is not possible to swallow the tablets whole, they can be split into two halves. In this case, the halves must be taken one after the other. This is the only way to ensure that the full dose is taken.





FORGOTTEN TABLET

Less than 18 hours:

Take the tablet as soon as possible. Then take the next dose at the regular time.

More than 18 hours:

Do not make up for the missed dose. Wait and take the next dose at the usual time.



VOMITING

Less than 1 hour after taking the tablet:

Take another dose.

More than 1 hour after taking the tablet:

Do not take any more tablets until you take the next dose at the usual time.



The right combination: BIKTARVY® and other medicines

BIKTARVY® is a long-term medication that can only work properly if it does not interact with other medications. It is therefore very important to talk to the attending physician before combining BIKTARVY® treatment with other medicines. This applies to prescription medicines, over-the-counter medicines and food supplements.

The following medicines should never be taken with BIKTARVY®:

Medicine	Area of application
Rifampicin	Treatment of bacterial infections, e.g. tuberculosis
St. John's wort	Anxiety, depression



The attending physicians can provide information about whether and how other medicines can be combined with BIKTARVY®. Warning: The following list does not replace the package insert or a consultation with a doctor.



A medical consultation is required for the following medicinal products and food supplements:

- ▶ Antiviral medicines to treat HIV and/or hepatitis B
- ▶ Antiviral medicines to treat hepatitis C
- ▶ Antacids to treat stomach ulcers, heartburn or acid reflux that contain aluminum and/or magnesium
- ▶ Minerals or vitamins that contain magnesium or iron
- ▶ Antibiotics to treat bacterial infections that contain one of the following active substances: azithromycin, clarithromycin, rifabutin, or rifapentine
- ▶ Anticonvulsants to treat epilepsy that contain the following active substances: carbamazepine, oxcarbazepine, phenobarbital, or phenytoin
- ▶ Immunosuppressants containing cyclosporine to suppress the response of the body's own immune system after a transplant
- ▶ Medicines that contain verapamil or dronedarone
- ▶ Medicines to treat ulcers that contain sucralfate
- ▶ Medicinal products or supplements that contain calcium and/or iron (during pregnancy)

Talk to your doctor if you are pregnant, breastfeeding or planning a pregnancy.



Doing the right thing in the event of side effects: what to do in the case of adverse reactions

Like all medicines, BIKTARVY® can have side effects, but not everybody gets them. If side effects occur while taking BIKTARVY®, after carefully reading the package insert, the attending physician should be consulted immediately.

A detailed list and extensive description of all possible side effects can be found in the package insert. More information about possible side effects is also available on [meine-hiv-therapie.de](https://www.meine-hiv-therapie.de).

Side effects can also be reported to the Federal Institute for Drugs and Medical Devices (Bundesinstitut für Arzneimittel und Medizinprodukte, BfArM), Kurt-Georg-Kiesinger-Allee 3, 53175 Bonn, fax no.: 0228/207-5207 or electronically via the website www.bfarm.de, or to Gilead Sciences GmbH, Drug Safety Department, email: Safety_FC@gilead.com, or via our international website on <https://www.gilead.com/contact-us/report-an-adverse-event>.



Precautions: minimizing the risk of transmission

Successful treatment that results in the viral load being permanently below the limit of detection means that HIV can no longer be transmitted via sexual intercourse.¹ The level of the limit of detection can vary depending on the test method used. For common detection processes it is < 50 copies/ml and corresponds to the treatment goals in the German and Austrian Guideline.² It is important to discuss whether all of the necessary requirements are met with the attending physician.



There are other sexually transmitted infections in addition to HIV, the transmission of which can be reduced by using condoms.^{1,2} Tests for other sexually transmitted infections could be a part of the regular check-up.

1. Epid Bull 2021; 47: 3 -17. doi: 10.25646/9301; 2. Guidelines for the Diagnosis and Treatment of HIV Infection from the German AIDS Society (DAIG). German and Austrian Guidelines. Available on: <https://daignet.de/leitlinien-und-empfehlungen/hiv-leitlinien/>, last accessed: August 2024.

Packed and ready to go:

BIKTARVY® when traveling

To make sure treatment is successful, there are some things worth considering in advance, both in everyday life and when traveling.



Checklist for traveling

- ☐ **Enough tablets for the entire duration of the trip:**
Acquire prescriptions early on and adjust your supply.
- ☐ **Backup in hand luggage:**
Carry a pack of BIKTARVY® with you in case there are problems with your checked bags.
- ☐ **Certificate to carry medications with you:**
Have a medical certificate on hand to prove that you need to carry it with you.
- ☐ **Consultation about the time you take the tablets:**
Although time differences should not cause any problems when taking BIKTARVY®: clarify the time you should take the tablets with your doctor to be sure. It should generally be the same as at home.
- ☐ **Prevent moisture:**
Store the tablets in the original packaging so they do not get moist.



Lasting wellbeing: attending regular check-ups

The attending physician is the most important point of contact for treatment with BIKTARVY®. The regular check-ups will include more than just a medical check of the blood work etc. The appointments can also be used for an entirely open discussion. No matter what, doctors will be there to offer you advice and support. They are subject to medical confidentiality.

Medical Information Service

Our Medical Information Service provides information about your disease in connection with the use of our medicines.

They would be happy to help you with questions such as

- How do you take the medicine properly?
- How do medicines work?
- Which side effects can occur?

Our Medical Information Service is available on the phone number: 089 899 8900 or via email to DEMedical.Information@gilead.com



Together, we have lots more planned

#nochvielvor



You can find lots of information on living with HIV and stories from other people in the community on **nochvielvor.de**.

An initiative of  **GILEAD** for living positively with HIV.

Note: This brochure cannot replace the package insert/package leaflet for BIKTARVY®, but it does contain important information from it. Please still read the package insert carefully before starting to take this medicine because it contains important information. Please direct any questions about BIKTARVY® to your doctor or pharmacist. Only to be given to patients prescribed BIKTARVY®. BIKTARVY® package leaflet, version of June 2024. Pictures are not of real patients, version of September 2024.

DE-BVY-0952