

## Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

▼ This medicine is new or being used differently. Please report side effects. See the [full CMI](#) for further details.

### 1. Why am I using BIKTARVY?

BIKTARVY contains the active ingredients bicitegravir, emtricitabine and tenofovir alafenamide in a single tablet. BIKTARVY is used to help control Human Immunodeficiency Virus 1 (HIV-1) infection in adults and children weighing at least 25 kg.

For more information, see Section [1. Why am I using BIKTARVY?](#) in the full CMI.

### 2. What should I know before I use BIKTARVY?

Do not use if you have ever had an allergic reaction to BIKTARVY or any of the ingredients listed at the end of the CMI.

**Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.**

For more information, see Section [2. What should I know before I use BIKTARVY?](#) in the full CMI.

### 3. What if I am taking other medicines?

Some medicines may interfere with BIKTARVY and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

### 4. How do I use BIKTARVY?

The usual dose is one BIKTARVY tablet orally, once daily. BIKTARVY tablets can be taken with or without food.

More instructions can be found in Section [4. How do I use BIKTARVY?](#) in the full CMI.

### 5. What should I know while using BIKTARVY?

<b>Things you should do</b>	<ul style="list-style-type: none"><li>Remind any doctor, dentist or pharmacist you visit that you are using BIKTARVY.</li></ul>
<b>Things you should not do</b>	<ul style="list-style-type: none"><li>Do not stop using this medicine suddenly.</li><li>Do not breastfeed.</li><li>Avoid doing things that can spread HIV infection.</li></ul>
<b>Driving or using machines</b>	<ul style="list-style-type: none"><li>Be careful driving or operating machinery until you know how BIKTARVY affects you.</li></ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"><li>Keep your BIKTARVY tablets in the bottle with the cap tightly closed until you take them.</li><li>Keep BIKTARVY tablets in a cool, dry place where it stays below 30 °C.</li></ul>

For more information, see Section [5. What should I know while using BIKTARVY?](#) in the full CMI.

### 6. Are there any side effects?

The most common side effects of BIKTARVY are diarrhoea and headache.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.



This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. You can report side effects to your doctor, or directly at [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems).

# BIKTARVY®

**Active ingredient(s):** *bictegravir, emtricitabine and tenofovir alafenamide*

## Consumer Medicine Information (CMI)

This leaflet provides important information about using BIKTARVY. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using BIKTARVY.**

**Where to find information in this leaflet:**

- [1. Why am I using BIKTARVY?](#)
- [2. What should I know before I use BIKTARVY?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use BIKTARVY?](#)
- [5. What should I know while using BIKTARVY?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

## 1. Why am I using BIKTARVY?

**BIKTARVY contains the active ingredients bictegravir, emtricitabine and tenofovir alafenamide in a single tablet.**

Bictegravir belongs to a group of antiretroviral medicines known as integrase strand transfer inhibitors (INSTI). Emtricitabine and tenofovir alafenamide belong to a group of antiviral medicines known as nucleoside and nucleotide reverse transcriptase inhibitors (NRTI) and (NtRTI), respectively.

These are combined in one tablet to help control Human Immunodeficiency Virus 1 (HIV-1) infection in adults and children weighing at least 25 kg.

**BIKTARVY is used to treat HIV-1 infection in adults and children weighing at least 25 kg.**

BIKTARVY lowers the amount of HIV in the blood (viral load). BIKTARVY may also help to increase the number of T cells (CD4+ cells), allowing your immune system to improve. Lowering the amount of HIV in the blood lowers the chance of death or infections that happen when your immune system is weak (opportunistic infections).

HIV infection destroys CD4+ T cells, which are important to the immune system. The immune system helps fight infection. After a large number of T cells are destroyed, acquired immune deficiency syndrome (AIDS) may develop.

BIKTARVY is for people who do not have a HIV virus resistant to BIKTARVY.

## 2. What should I know before I use BIKTARVY?

### Warnings

**Do not use BIKTARVY if:**

- you are allergic to bictegravir, emtricitabine or tenofovir alafenamide, or any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can use this medicine.
- you are already taking any other medicines that contain the same active ingredients.
- you are taking other medicines that contain:
  - tenofovir disoproxil fumarate (e.g. Truvada, Viread)
  - tenofovir alafenamide (e.g. Descovy, Genvoya, Odefsey, Vemlidy)
  - emtricitabine (e.g. Descovy, Emtriva, Genvoya, Odefsey)
  - lamivudine (e.g. Combivir, Triumeq)
- you are also taking dofetilide to treat heart conditions.
- you are also taking rifampicin to treat infections.
- you are also taking adefovir dipivoxil to treat your hepatitis B virus (HBV) infection.

**Check with your doctor if you:**

- Have kidney problems or are undergoing kidney dialysis treatment.
  - Your doctor should do blood and urine tests to check your kidneys when starting and during treatment with BIKTARVY. Your doctor may tell you to stop taking BIKTARVY if you develop new or worse kidney problems.
- Have liver problems, including hepatitis B or C virus infection.
- Take any medicines for any other condition

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

### Pregnancy and Breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant. We do not know if BIKTARVY can harm your unborn child. You and your doctor will need to decide if BIKTARVY is right for you.

Talk to your doctor if you are breastfeeding or intend to breastfeed. You should not breastfeed if you are HIV-positive because of the chance of passing the HIV virus to your baby. At least one of the active substances in this medicine (emtricitabine) has been found in breast milk at low concentrations. Talk with your doctor about the best way to feed your baby.

### Use in Children

- The use of BIKTARVY in children weighing less than 25kg has not yet been established.

### Does BIKTARVY cure HIV, AIDS or HBV

**BIKTARVY does not cure HIV infection, AIDS or HBV infection.**

The long-term effects of BIKTARVY are not known at this time.

People taking BIKTARVY or any other medication for HIV may still get opportunistic infections or other conditions that happen with HIV infection.

Opportunistic infections are infections that develop because the immune system is weakened. Some of these conditions are pneumonia, herpes virus infections, and *Mycobacterium avium complex* (MAC) infection.

**This medicine is only available from a pharmacist after it has been prescribed by a doctor who specialises in the treatment of HIV infection.**

**If you wish to continue receiving treatment with BIKTARVY it is important you remain under the care of a hospital or doctor who specialises in the treatment of HIV infection.**

### Does BIKTARVY reduce the risk of passing HIV to others

**Effective viral suppression with BIKTARVY will substantially reduce the risk of passing HIV to others. However, a residual risk cannot be excluded.**

**Discuss with your doctor the precautions needed to avoid infecting other people.**

For your health and the health of others, it is important to always practice safer sex by using a latex or polyurethane condom or other barrier to lower the chance of sexual contact with semen, vaginal secretions, or blood.

**Never re-use or share needles.**

## 3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Tell your doctor if you take any of the following medicines:

- carbamazepine (e.g. Tegretol)
- oxcarbazepine (e.g. Trileptal)
- phenobarbital or phenytoin (e.g. Dilantin)

- rifabutin (e.g. Mycobutin)
- rifapentine (e.g. Priftin)
- boceprevir (e.g. Victrelis)
- St John's Wort or products containing St John's Wort
- atazanavir (e.g. Reyataz)

This is not a complete list of medicines that you should tell your doctor about.

These medicines may be affected by BIKTARVY or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

For this reason, it is very important to let your doctor or pharmacist know what medications, herbal supplements, or vitamins you are taking.

**Know the medicines you take. Keep a list of medicines and show it to your doctor and pharmacist when you get a new medicine.**

**Do not start any new medicines while you are taking BIKTARVY without first talking with your doctor or pharmacist.**

**Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect BIKTARVY.**

## 4. How do I use BIKTARVY?

### How much to take

- The usual dose is one BIKTARVY tablet orally, once daily.
- Take BIKTARVY with or without food.
- If you are on dialysis, take your daily dose of BIKTARVY following dialysis.
- Do not chew, crush or split the tablet.
- Follow the instructions provided and use BIKTARVY until your doctor tells you to stop.

### When to take it

- If you are taking an antacid (such as aluminium/magnesium hydroxide), a mineral supplement or vitamin (containing calcium or iron), ulcer-healing medication (such as sucralfate), or a buffered medication (containing calcium carbonate), take BIKTARVY at least 2 hours before taking these medications.
- Alternatively, you can take the medication and BIKTARVY together with food.

### If you forget to use BIKTARVY

BIKTARVY should be used regularly at the same time each day.

It is important not to miss a dose of BIKTARVY.

If you do miss a dose:

- **If you notice within 18 hours** of the time you usually take BIKTARVY, you must take the tablet as soon as possible. Then take the next dose as usual.

- **If you notice 18 hours or more** after the time you usually take BIKTARVY, then do not take the missed dose. Wait and take the next dose at your usual time

**Do not take a double dose to make up for a forgotten dose.**

Continue with your regular dosing schedule.

**When your BIKTARVY supply starts to run low, get more from your doctor 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 BIKTARVY and become harder to treat.

**If you use too much BIKTARVY**

If you think that you have used too much BIKTARVY, you may need urgent medical attention.

**You should immediately:**

- phone the Poisons Information Centre (by calling 13 11 26), or
- phone the National Poisons Centre 0800 764 766 (New Zealand)
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

**You should do this even if there are no signs of discomfort or poisoning.**

## 5. What should I know while using BIKTARVY?

### Things you should do

Remind any doctor, dentist or pharmacist you visit that you are using BIKTARVY.

### Things you should not do

- Do not stop using this medicine suddenly.
- **Do not breastfeed.**
- **Avoid doing things that can spread HIV infection.**
  - **Do not share needles or other injection equipment.**
  - **Do not share personal items that can have blood or body fluids on them, like toothbrushes or razor blades.**
- Always practice safer sex by using a latex or polyurethane condom or other barrier to reduce the chance of sexual contact with semen, vaginal secretions, or blood.
- **Do not take BIKTARVY if the packaging is torn or shows signs of tampering.**

### Driving or using machines

**Be careful before you drive or use any machines or tools until you know how BIKTARVY affects you.**

If you are dizzy, have trouble concentrating, or are drowsy, avoid activities that may be dangerous, such as driving or operating machinery.

## Looking after your medicine

- Keep your BIKTARVY tablets in the bottle with the cap tightly closed until you take them. If you take BIKTARVY tablets out of their pack they may not keep well.
- Store BIKTARVY tablets in a cool, dry place where it stays below 30 °C.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

**Keep it where young children cannot reach it.**

## When to discard your medicine (as relevant)

**Do not take BIKTARVY after the expiry or “use by” date (EXP) printed on the bottle.** If you take it after the expiry date has passed, it may not work as well.

## Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

## 6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

## Less serious side effects

Less serious side effects	What to do
<ul style="list-style-type: none"> <li>• diarrhoea</li> <li>• headache</li> <li>• nausea</li> <li>• tiredness (fatigue)</li> <li>• abdominal pain</li> <li>• indigestion</li> <li>• wind (flatulence)</li> <li>• rash</li> <li>• vomiting</li> <li>• abnormal dreams</li> <li>• suicidal behaviour</li> <li>• anxiety</li> <li>• sleep disorders</li> <li>• depression</li> </ul>	<p><b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b></p>

## Serious side effects

Serious side effects	What to do
<p><b>Allergy</b> Signs of allergic reaction such as:</p> <ul style="list-style-type: none"> <li>• Skin troubles such as lumpy skin rash or “hives”</li> <li>• Swelling of the face, lips, mouth, or throat which may cause difficulty in swallowing or breathing</li> <li>• Wheezing, chest pain, or tightness</li> <li>• Fainting</li> </ul> <p><b>Hepatic Flares</b></p> <p>If you have both HIV infection and HBV infection you should not stop your BIKTARVY treatment without first discussing this with your doctor. Your HBV may get worse (flare-up) if you stop taking BIKTARVY. A “flare-up” or “hepatic flare” is when your HBV infection suddenly returns in a worse way than before. You may require medical exams and blood tests for several months after stopping treatment.</p> <p><b>Signs and symptoms of inflammation</b></p> <p>In some patients with advanced HIV infection (AIDS), signs and symptoms of inflammation from previous infections may occur soon after anti-HIV treatment is started. It is believed that these symptoms are due to an improvement in the body’s immune response, which lets the body fight infections that may have</p>	<p><b>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</b></p>

been present with no obvious symptoms. If you notice any symptoms of infection, please tell your doctor immediately.	
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**Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.**

Other side effects not listed here may occur in some people.

**Ask your doctor or pharmacist for a more complete list of side effects of BIKTARVY and all the medicines you will take.**

### Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems) in Australia or to <https://pophealth.my.site.com/carmreportnz/s/> in New Zealand. By reporting side effects, you can help provide more information on the safety of this medicine.

**Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.**

## 7. Product details

This medicine is only available with a doctor's prescription.

### What BIKTARVY contains

<b>Active ingredient (main ingredient)</b>	bictegravir (as sodium) emtricitabine tenofovir alafenamide
<b>Other ingredients (inactive ingredients)</b>	microcrystalline cellulose croscarmellose sodium magnesium stearate polyvinyl alcohol titanium dioxide macrogol 3350 purified talc Opadry II Brown
<b>Potential allergens</b>	N/A

**Do not take this medicine if you are allergic to any of these ingredients.**

### What BIKTARVY looks like

BIKTARVY tablets are capsule-shaped, purplish-brown in colour and film-coated.

Each tablet is debossed with “GSI” on one side and the number “9883” on the other side.

BIKTARVY tablets are supplied in bottles containing 30 tablets.

## **Who distributes BIKTARVY**

### Australia

Gilead Sciences Pty Ltd  
Level 28, 385 Bourke Street  
Melbourne, Victoria 3000

### New Zealand

c/- Grant Thornton New Zealand Limited,  
L4, 152 Fanshawe Street  
Auckland 1010

This leaflet was prepared in September 2024.

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