Patient Information Leaflet

SCHEDULING STATUS

S4

BIKTARVY 50 mg/200 mg/25 mg film coated tablets

bictegravir/emtricitabine/tenofovir alafenamide

Read all of this leaflet carefully before you start taking BIKTARVY

- Keep this leaflet. You may need to read it again.
- Do not share **BIKTARVY** with any other person.
- Ask your health care provider or pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve.

If BIKTARVY has been prescribed for your child, please note that all the information in this leaflet is addressed to your child (in this case please read "your child" instead of "you".

What is in this leaflet

1. What **BIKTARVY** is and what it is used for
2. What you need to know before you take **BIKTARVY**
3. How to take **BIKTARVY**
4. Possible side effects
5. How to store **BIKTARVY**

6. Contents of the pack and other information

1. What BIKTARVY is and what it is used for

BIKTARVY is a single tablet for the treatment of human immunodeficiency virus-1 (HIV-1) infection in adults, adolescents and children 6 years of age and older, who weigh at least 25 kg, who have no antiretroviral treatment history or to replace the current antiretroviral regimen in those who are virologically suppressed on a stable antiretroviral regimen for at least 3 months.

BIKTARVY reduces the amount of HIV in your body. This will improve your immune system and reduce the risk of developing illnesses linked to HIV infection.

BIKTARVY contains three active substances

- **bictegravir,** an antiretroviral medicine known as an integrase strand transfer inhibitor (INSTI)
- **emtricitabine**, an antiretroviral medicine of a type known as a nucleoside
- **tenofovir alafenamide**, an antiretroviral medicine of a type known as a nucleotide reverse transcriptase inhibitor (NtRTI).

2. What you need to know before you take BIKTARVY

Do not take BIKTARVY

- If you are allergic to bictegravir, emtricitabine, tenofovir alafenamide or any of the other ingredients of **BIKTARVY** (listed in section 6 of this leaflet).

- **If you are taking one of these medicines:**
  - dofetilide, an antidysrhythmic medicine.
  - rifampicin and rifamycin used to treat some bacterial infections such as tuberculosis.
  - If you are treated with/taking St John's wort (*Hypericum perforatum)*, a herbal remedy used for depression and anxiety, or medicines that contain it.
  - If you are pregnant, planning to become pregnant or are breastfeeding your baby.

→ If any of these apply to you, **do not take BIKTARVY and tell your doctor immediately.**

Warnings and precautions

Take special care with BIKTARVY:

- **If you have liver problems or a history of liver disease, including hepatitis**. Patients with liver disease including chronic hepatitis B or C, who are treated with antiretrovirals, have a higher risk of severe and potentially fatal liver complications.
- **If you have hepatitis B infection**, your doctor will carefully consider the best treatment regimen for you.
  Liver problems may become worse after you stop taking BIKTARVY. Do not stop taking BIKTARVY if you have hepatitis B. Talk to your doctor first.
- **If you have had kidney disease or if tests have shown problems with your kidneys,** your doctor may order blood tests

to monitor how your kidneys work when starting and during treatment with **BIKTARVY**.

- **You can still pass on HIV** when taking **BIKTARVY**. Discuss with your doctor the precautions needed to avoid infecting other people. **BIKTARVY** is not a cure for HIV infection. While taking **BIKTARVY** you may still develop infections or other illnesses associated with HIV infection.

- Once you start taking **BIKTARVY**, look out for:

- Signs of inflammation or infection
- Joint pain, stiffness or bone problems.

If you notice any of these symptoms, tell your doctor immediately. For more information see section 4.

There is a possibility that you may experience kidney problems when taking **BIKTARVY** over a long period of time *(see Warnings and Precautions*).

Children and adolescents

Do not give **BIKTARVY** to children and adolescents weighing less than 25 kg regardless of age. The use of **BIKTARVY** in children under 6 years of age, or weighing less than 25 kg has not yet been established.

Loss of bone mass has been reported in some children from 6 to less than 12 years of age who received one of the active substances (tenofovir alafenamide) contained in BIKTARVY. The effects on long term bone

health and future fracture risk in children is uncertain. Your doctor will monitor your child's bone health as needed.

Other medicines and BIKTARVY

Always tell your health care provider if you are taking any other medicines. (This includes all complementary or traditional medicines.)

DO NOT take **BIKTARVY** if you are taking any of the following medicines

- dofetilide, a medicine used to treat heart rhythm disorders
- rifampicin and rifamycin used to treat some bacterial infections such as tuberculosis,
- St John's wort (*Hypericum perforatum*), a herbal remedy used for depression and anxiety, or medicines that contain it.

Tell your doctor immediately if you are taking any of these medicines.

Talk to your doctor if you are taking:

- medicines used for treating HIV and/or hepatitis B, containing
    - adefovir dipivoxil, atazanavir, bictegravir, emtricitabine, lamivudine, tenofovir alafenamide, or tenofovir disoproxil,
- antibiotics used to treat bacterial infections, containing:
    - azithromycin, clarithromycin, rifabutin or rifapentine,
- anticonvulsants used to treat epilepsy, containing:
    - carbamazepine, oxcarbazepine, phenobarbitone and phenytoin,
- immunosuppressants used to control your body's immune response after a transplant, containing ciclosporin,
- ulcer-healing medicines containing sucralfate,

Tell your doctor if you are taking these or any other medicines. Do not stop your treatment without contacting your doctor.

Talk to your doctor if you are taking:

- antacids to treat stomach ulcers, heartburn, or acid reflux, containing aluminium and/or magnesium hydroxide,
- mineral supplements or vitamins containing magnesium or iron.

Talk to your doctor before taking BIKTARVY if you are taking any of these medicines:

- Antacids and supplements containing aluminium and/or magnesium: you will need to take **BIKTARVY** at least 2 hours before antacids or supplements containing aluminium and/or magnesium. Or you can take **BIKTARVY** with food at least 2 hours after. However, if you are pregnant see *Pregnancy and breast-feeding.*
- Iron supplements: you will need to take **BIKTARVY** at least 2 hours before iron supplements, or you can take them together with food at any time. However, if you are pregnant see *Pregnancy and breast-feeding*.

BIKTARVY with food and drink

BIKTARVY can be taken with or without food.

Pregnancy and breast-feeding

- If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking **BIKTARVY.**

- Tell your doctor immediately if you become pregnant and ask about the potential benefits and risks of your antiretroviral therapy to you and your child.
    - **Antacids and supplements containing aluminium and/or magnesium:** during your pregnancy you will need to take Biktarvy at least 2 hours before or 6 hours after taking antacids, medicines or supplements containing aluminium and/or magnesium.
    - **Supplements or medicines containing calcium and/or iron:** during your pregnancy you will need to take Biktarvy at least 2 hours before or 6 hours after taking supplements or medicines containing calcium and/or iron. Alternatively, you can take them together with food at any time.
- **If you have taken BIKTARVY during your pregnancy,** your doctor may request regular blood tests and other diagnostic tests to monitor the development of your child.
- **Use effective contraception** while taking **BIKTARVY.**
- **Do not breast-feed your baby during treatment with BIKTARVY**. This is because some of the active substances in **BIKTARVY** pass into human breast milk. If you are breast-feeding, or thinking about breast-feeding, you should discuss it with your doctor as soon as possible.

Driving and using machines

BIKTARVY can cause dizziness. If you feel dizzy when taking **BIKTARVY**, do not drive or ride a bicycle and do not use any tools or machines.

3. How to take BIKTARVY

Do not share medicines prescribed for you with any other person.

Always take BIKTARVY, **exactly as your doctor has told you.** Check with your doctor or pharmacist if you are not sure.

BIKTARVY is for oral use.

Adults:

The recommended dose is one tablet once daily, with or without food.

Due to the bitter taste, it is recommended not to chew or crush the tablet.

If you have difficulty swallowing the tablet whole, you can split it in half. Take both halves of the tablet one after the other to get the full dose. Do not store the split tablet.

Get advice from a doctor or pharmacist if you are taking:

- **antacids** to treat stomach ulcers, heartburn, or acid reflux, containing aluminium and/or magnesium hydroxide
- **mineral supplements or vitamins** containing magnesium or iron

See section 2 for more information on taking these medicines with BIKTARVY.

If you are on dialysis, take your daily dose of **BIKTARVY** following completion of dialysis.

If you vomit less than 1 hour after taking **BIKTARVY**, take another tablet.

If you vomit more than 1 hour after taking **BIKTARVY** you do not need to take another tablet until your next regularly scheduled tablet.

If you take more BIKTARVY than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

If you accidentally take more than the recommended dose of **BIKTARVY** you may be at increased risk of experiencing possible side effects. Contact your doctor or nearest emergency department immediately for advice.

Keep the tablet bottle with you so that you can show what you have taken.

If you forget to take BIKTARVY

It is important not to miss a dose of **BIKTARVY.** If you miss a dose, work out how long since you should have taken it.

- If it is less than 18 hours after you usually take **BIKTARVY**, take it as soon as you can, and then take your next dose at its regular time.
- If it is more than 18 hours after you usually take **BIKTARVY**, then do not take the missed dose. Wait and take the next dose at the regular time. Do not take a double dose to make up for a forgotten tablet.

Do not stop taking BIKTARVY

Do not stop taking BIKTARVY without talking to your doctor.

Stopping **BIKTARVY** can seriously affect how future treatment works. If **BIKTARVY** is stopped for any reason, speak to your doctor before you restart taking **BIKTARVY** tablets.

When your supply of BIKTARVY starts to run low, get more from your doctor or pharmacist. This is very important because the amount of virus may start to increase if **BIKTARVY** is stopped for even a short time. The disease may then become harder to treat.

If you have both HIV infection and hepatitis B, it is especially important not to stop your **BIKTARVY** treatment without talking to your doctor first. You may require blood tests for several months after stopping treatment. In some patients with advanced liver disease or cirrhosis, stopping treatment is not recommended as this may lead to worsening of your hepatitis, which may be life-threatening.

Talk to your doctor immediately about new or unusual symptoms after you stop treatment, particularly symptoms you associate with hepatitis B infection.

If you have any further questions on the use of this medicine, ask your doctor.

4. Possible side effects

BIKTARVY can have side effects.

Not all side effects reported for **BIKTARVY** are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking **BIKTARVY**, please consult your health care provider for advice.

If any of the following happens, stop taking BIKTARVY and tell your doctor immediately or go to the casualty department at your nearest hospital:

- rash

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to **BIKTARVY**. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- **Any signs of inflammation or infection.** In some patients with advanced HIV infection (AIDS) and a history of opportunistic infections (infections that occur in people with a weak immune system), signs and symptoms of inflammation from previous infections may occur soon after HIV treatment is started. It is thought that these symptoms are due to an improvement in the body's immune response, enabling the body to fight infections that may have been present with no obvious symptoms.
- **Autoimmune disorders**, when the immune system attacks healthy body tissue, may also occur after you start taking medicines for HIV infection. Autoimmune disorders may occur many months after the start of treatment. Look out for any symptoms of infection or other symptoms such as:
  - muscle weakness
  - weakness beginning in the hands and feet and moving up towards the trunk of the body

- palpitations, tremor or hyperactivity.

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Common side effects

- depression
- abnormal dreams
- headache
- dizziness
- diarrhoea
- nausea (feeling sick)
- tiredness (fatigue)

Uncommon side effects

- anaemia
- vomiting
- stomach pain
- problems with digestion resulting in discomfort after meals (dyspepsia)
- wind (flatulence),
- swelling of the face, lips, tongue or throat (angioedema)
- itching (pruritus)
- rash
- hives (urticaria)
- joint pain (arthralgia)
- suicidal thoughts and suicide attempt (particularly in patients who have had depression or mental health problems before)

- anxiety
- sleep disorders

Rare side effects

- Stevens-Johnson syndrome (SJS) is a serious life-threatening condition which usually starts with flu-like symptoms. A few days later other symptoms appear including:
    - Painful red or purple skin that looks burned and peels off
    - Blisters on your skin, mouth, nose, and genitals
    - Red, painful, watery eyes

If you have any of these symptoms, stop your medicine immediately and tell your doctor straight away.

Blood tests may also show

- higher levels of substances called bilirubin and/or serum creatinine in the blood

If any of the side effects get serious, tell your doctor.

Other effects that may be seen during HIV treatment

The frequency of the following side effects is not known (frequency cannot be estimated from the available data).

- **Bone problems.** Some patients taking combination antiretroviral medicines such as **BIKTARVY** may develop a bone disease called *osteonecrosis* (death of bone tissue caused by loss of blood supply to the bone). Taking this type of medicine for a long time, taking corticosteroids, drinking alcohol, having a weak immune

system, and being overweight, may be some of the many risk factors for developing this disease.

Signs of osteonecrosis are:

- joint stiffness
- joint aches and pains (especially of the hip, knee and shoulder)
- difficulty with movement.

Blood tests may also show:

- higher levels of substances called bilirubin and/or serum creatinine in the blood.

During HIV therapy there may be an increase in weight and in levels of blood lipids and glucose. This is partly linked to restored health and lifestyle and the HIV medicines such as **BIKTARVY**. Your doctor will test for these changes.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

→ **If you notice any of these symptoms tell your doctor.**

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of **BIKTARVY**.

5. How to store BIKTARVY

- Store all medicines out of reach of children.

- Do not use this medicine after the expiry date which is stated on the bottle and carton after {EXP}. The expiry date refers to the last day of that month.
- Store in the original package in order to protect from moisture.
- Keep the bottle tightly closed.
- Store at or below 30 °C.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What BIKTARVY contains

The active substances are bictegravir, emtricitabine and tenofovir alafenamide. Each **BIKTARVY** film-coated tablet contains 50 mg of bictegravir, 200 mg of emtricitabine and tenofovir alafenamide fumarate equivalent to 25 mg of tenofovir alafenamide.

The other ingredients are

Tablet core: Croscarmellose sodium, magnesium stearate, microcrystalline cellulose

Film-coating: Iron oxide red (E172), iron oxide black (E172), polyethylene glycol, polyvinyl alcohol, titanium dioxide (E171), talc.

What BIKTARVY looks like and contents of the pack

BIKTARVY film-coated tablets are Purplish-brown, capsule-shaped, film-coated tablet debossed with “GSI” on one side and “9883” on the other side of the tablet. Each tablet is approximately 15 mm x 8 mm.

BIKTARVY tablets are packaged in a white, high-density polyethylene (HDPE) bottle with a polypropylene continuous thread, child resistant cap, lined with an induction activated aluminium foil liner containing 30 film coated tablets. Each bottle contains silica gel desiccant and polyester coil.

Holder of Certificate of Registration and Manufacturer

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This leaflet was last revised in

19 November 2025

Registration number

53/20.2.8/0454

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Date: 2025.11.26 12:36:59 +02'00'