GENVOYA®

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.

1. Why am I using GENVOYA?

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

For more information, see Section 1. Why am I using GENVOYA? in the full CMI.

2. What should I know before I use GENVOYA?

Do not use if you have ever had an allergic reaction to GENVOYA 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 GENVOYA? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with GENVOYA 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 GENVOYA?

- The usual dose is one GENVOYA tablet orally, once daily with food.

More instructions can be found in Section 4. How do I use GENVOYA? in the full CMI.

5. What should I know while using GENVOYA?

Things you should do	• Remind any doctor, dentist or pharmacist you visit that you are using GENVOYA.
Things you should not do	• Do not stop using this medicine suddenly. • Do not breastfeed. • Avoid doing things that can spread HIV infection.
Driving or using machines	• Be careful driving or operating machinery until you know how GENVOYA affects you.
Looking after your medicine	• Keep your GENVOYA tablets in the bottle with the cap tightly closed until you take them. • Keep GENVOYA tablets in a cool, dry place where it stays below 25°C.

For more information, see Section 5. What should I know while using GENVOYA? in the full CMI.

6. Are there any side effects?

The most common side effect of GENVOYA is nausea.

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.

GENVOYA®

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

Consumer Medicine Information (CMI)

This leaflet provides important information about using GENVOYA. **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 GENVOYA.**

Where to find information in this leaflet:

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

1. Why am I using GENVOYA?

GENVOYA contains the active ingredients elvitegravir, cobicistat, emtricitabine and tenofovir alafenamide in a single tablet.

Elvitegravir belongs to a class of antiviral medicines known as integrase inhibitors.

Cobicistat is a "booster", to help increase the levels of elvitegravir.

Emtricitabine and tenofovir alafenamide belong to a group of antiviral medicines known as nucleoside and nucleotide reverse transcriptase inhibitors (NRTI).

GENVOYA is used to treat Human Immunodeficiency Virus 1 (HIV-1) infection in adults and children weighing at least 25 kg.

GENVOYA helps block HIV-1 reverse transcriptase, a viral chemical in your body (enzyme) that is needed for HIV-1 to multiply.

GENVOYA lowers the amount of HIV in the blood (viral load). GENVOYA 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.

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

2. What should I know before I use GENVOYA?

Warnings

Do not use GENVOYA if:

- you are allergic to elvitegravir, cobicistat, 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:
  - lamivudine (e.g. Combivir, Zeffix, Kivexa, Trizivir, Triumeq)
  - ritonavir (e.g. Kaletra)
  - tenofovir disoproxil fumarate (e.g. Viread)
  - Efavirenz (e.g. Stocrin)
- you take:
  - alfuzosin hydrochloride (e.g. Xatral),
  - carbamazepine (e.g. Tegretol),
  - phenobarbital or phenytoin (e.g.Dilantin),
  - ergot-containing medicines like dihydroergotamine, ergotamine (e.g. Cafergot, Dihydergot, Migerot).
  - lovastatin (e.g. Mevacor)
  - midazolam (e.g.Hypnovel)
  - rifabutin (e.g.Mycobutin)
  - sildenafil (e.g. Viagra/Revatio)
  - simvastatin (e.g. Invast/Zimcol)
  - tadalafil (e.g.Cialis/Adcirca)
  - triazolam (e.g.Halcion)
  - rifampicin (e.g. Rifadin/Rimycin)
  - St John's Wort or products containing St John's Wort.
- you are also taking adefovir dipivoxil to treat your hepatitis B (HBV) infection

This is not a complete list of medicines that you should not take with GENVOYA. You should discuss this with your doctor.

Check with your doctor if you:

- have severe 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 GENVOYA. Your doctor may tell you to stop taking GENVOYA if you develop new or worse kidney problems.
- have 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 GENVOYA can harm your unborn child. You and your doctor will need to decide if GENVOYA 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. 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 and Elderly

- GENVOYA is used to treat HIV-1 infection in adults and children 6 years of age and older.
- GENVOYA has not been studied in children under the age of 6 or weighing less than 25 kg, or adults over the age of 65.
- GENVOYA has not been studied in children and adolescents under the age of 18 who have both HIV-1 and HBV infections.

Does GENVOYA Cure HIV, AIDS or HBV?

GENVOYA does not cure HIV infection or AIDS.

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

People taking GENVOYA 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 GENVOYA it is important you remain under the care of a hospital or doctor who specialises in the treatment of HIV infection.

Does GENVOYA reduce the risk of passing HIV to others?

It is still possible to pass on HIV to other people through sexual contact, sharing needles, or being exposed to your blood when taking GENVOYA, although the risk is much lower with effective antiretroviral therapy.

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 of 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.

Some medicines may affect the levels of GENVOYA or GENVOYA may affect the levels of other medicines in the body when they are taken at the same time as GENVOYA.

Your doctor may change your other medicines or change their doses. Other medicines, including herbal products may affect GENVOYA.

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.

Your doctor and your pharmacist can tell you if you can take these medicines with GENVOYA.

Do not start any new medicines while you are taking GENVOYA 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 GENVOYA.

4. How do I use GENVOYA?

How much to take

- The usual dose is one GENVOYA tablet orally, once daily.
- Take GENVOYA with food.
- Follow the instructions provided and use GENVOYA until your doctor tells you to stop.

If you forget to use GENVOYA

GENVOYA should be used regularly at the same time each day. It is important not to miss a dose of GENVOYA. If you miss your dose at the usual time, take your missed dose right away unless it is almost time for your next dose.

Do not take a double dose to make up for the dose you missed.

Continue with your regular dosing schedule.

When your GENVOYA 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 GENVOYA and become harder to treat.

If you use too much GENVOYA

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

You should immediately:

- phone the Poisons Information Centre **by calling 13 11 26 (Australia) and 0800 764 766 (New Zealand)**, or
- 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 GENVOYA?

Things you should do

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

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 GENVOYA 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 GENVOYA 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 GENVOYA tablets in the bottle with the cap tightly closed until you take them. If you take GENVOYA tablets out of their pack, they may not keep well.
- Keep GENVOYA in a cool, dry place where it stays below 25°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

Do not take GENVOYA 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
• nausea • diarrhoea • fatigue • headaches • abdominal pain • indigestion • flatulence • rash • vomiting	**Speak to your doctor if you have any of these less serious side effects and they worry you.**

Serious side effects

Serious side effects	What to do
Hepatic Flares If you have HIV infection and HBV infection you should not stop your GENVOYA treatment without first discussing this with your doctor. Your HBV may get worse (flare-up) if you stop taking GENVOYA. 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. GENVOYA is not	**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.**

approved for the treatment of HBV, so you must discuss your HBV therapy with your doctor.

Signs and Symptoms of Inflammation

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 been present with no obvious symptoms. If you notice any symptoms of infection, please tell your doctor immediately.

Lactic Acidosis

- you feel very weak or tired
- you have unusual (not normal) muscle pain
- you have trouble breathing
- you have stomach pain with nausea and vomiting
- you feel cold, especially in your arms and legs
- you feel dizzy or light headed
- you have a fast or irregular heartbeat

These side effects may be due to a condition called lactic acidosis (build-up of an acid in the blood).

Lactic acidosis can be a medical emergency and may need to be treated in the hospital.

Serious Liver Problems (hepatotoxicity)

- your skin or the white part of your eyes turns yellow (jaundice)
- your urine turns dark
- your bowel movements (stools) turn light in colour
- you don't feel like eating food for several days or longer
- you feel sick to your stomach (nausea)
- you have lower stomach area (abdominal) pain

These side effects may be due to a condition called hepatotoxicity with liver enlargement (hepatomegaly) and fat deposits in the liver (steatosis) which sometimes occurs in patients taking anti-HIV medicines.

Allergy

Some people are allergic to medicines. If you have any of the following symptoms soon after taking your medicine, DO NOT TAKE ANY MORE GENVOYA and tell your doctor IMMEDIATELY or go to the accident and emergency department at your nearest hospital:

- skin troubles such as lumpy skin rash or "hives"
- swelling of the face, lips, mouth or throat which may cause difficulty in swallowing or breathing
- wheezing, chest pain or tightness
- fainting

These are very serious effects. If you have them, you may have a serious allergic reaction. You may need urgent medical attention or hospitalisation. Hypersensitivity reactions are very rare.

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 GENVOYA 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. 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 GENVOYA contains

Active ingredient (main ingredient)	elvitegravir cobicistat emtricitabine tenofovir alafenamide
Other ingredients (inactive ingredients)	lactose microcrystalline cellulose croscarmellose sodium hyprolose silicon dioxide sodium lauryl sulfate magnesium stearate polyvinyl alcohol titanium dioxide polyethylene glycol talc indigo carmine aluminum lake iron oxide yellow
Potential allergens	N/A

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

What GENVOYA looks like

GENVOYA tablets are capsule-shaped, film-coated and green in colour.

Each tablet is debossed with “GSI” on one side and the number “510” on the other side.

GENVOYA tablets are supplied in bottles containing 30 tablets.

AUST R 233398

Who distributes GENVOYA

Australia

Gilead Sciences Pty Ltd

Level 28, 385 Bourke Street

Melbourne, Victoria, 3000

New Zealand

c/o Tompkins Wake

Level 17, 88 Shortland Street,

Auckland, 1010,

New Zealand

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