

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 DESCOVY?

DESCOVY contains the active ingredients emtricitabine and tenofovir alafenamide. DESCOVY is used to:

- treat Human Immunodeficiency Virus-1 (HIV-1) infection in adults and paediatric patients weighing ≥ 25 kg when taken in combination with other anti-HIV medicines
- to reduce the risk of getting HIV-1 infection in at-risk adults and adolescents weighing ≥ 35 kg

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

2. What should I know before I use DESCOVY?

Do not use if you have ever had an allergic reaction to DESCOVY 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 DESCOVY?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with DESCOVY 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 DESCOVY?

- The usual dose is one DESCOVY tablet orally, once daily.
- Take DESCOVY with or without food.

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

5. What should I know while using DESCOVY?

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

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

6. Are there any side effects?

The most common side effect of DESCOVY 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.



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.

DESCOVY®

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

Consumer Medicine Information (CMI)

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

Where to find information in this leaflet:

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

1. Why am I using DESCOVY?

DESCOVY contains the active ingredients emtricitabine and tenofovir alafenamide in one tablet.

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

DESCOVY is used to:

- treat Human Immunodeficiency Virus-1 (HIV-1) infection in adults and paediatric patients weighing ≥ 25 kg when taken in combination with other anti-HIV medicines
- reduce the risk of getting HIV-1 infection in at-risk adults and adolescents weighing ≥ 35 kg

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

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

DESCOVY 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.

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

2. What should I know before I use DESCOVY?

Warnings

Do not use DESCOVY if:

- you are allergic to 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 take:
 - tenofovir disoproxil fumarate (e.g. VIREAD)
 - lamivudine (e.g. Combivir, Zeffix, Kivexa, Trizivir, Triumeq)
 - carbamazepine (e.g. Tegretol)
 - oxcarbazepine (e.g. Trileptal)
 - phenobarbital or phenytoin (e.g. Dilantin)
 - rifabutin (e.g. Mycobutin)
 - rifampicin (e.g. Rifadin/Rimycin)
 - rifapentine (e.g. Priftin)
 - St John's Wort or products containing St John's Wort
 - tipranavir (e.g. Aptivus)
 - boceprevir (e.g. Victrelis)
- you are also taking adefovir dipivoxil to treat your hepatitis B virus (HBV) infection.

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

Check with your doctor if you:

- 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 DESCOVY. Your doctor may tell you to stop taking DESCOVY if you develop new or worse kidney problems.
- 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 DESCOVY can harm your unborn child. You and your doctor will need to decide if DESCOVY 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) have been found in breast milk at low concentrations. It is not known if DESCOVY affects milk production or has effects on the breastfed child. Talk with your doctor about the best way to feed your baby.

Use in Children

DESCOVY is used to treat HIV-1 infection in adults and children weighing ≥ 25 kg.

DESCOVY is used to reduce the risk of getting HIV-1 in adolescents weighing ≥ 35 kg.

DESCOVY has not been studied in children weighing less than 25 kg.

Does DESCOVY cure HIV or AIDS?

DESCOVY does not cure HIV infection or AIDS.

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

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

Does DESCOVY reduce the risk of passing HIV to others?

DESCOVY 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.

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

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

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 DESCOVY.

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

4. How do I use DESCOVY?

How much to take

- The usual dose is one DESCOVY tablet orally, once daily.
- Take DESCOVY with or without food.

If you forget to use DESCOVY

DESCOVY should be used regularly at the same time each day. It is important not to miss a dose of DESCOVY.

If you do miss a dose:

- **If you notice within 18 hours** of the time you usually take DESCOVY, 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 DESCOVY, 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 the dose you missed.

Continue with your regular dosing schedule.

When your DESCOVY supply starts to run low, get more from your doctor or pharmacy.

This is very important. If you are taking DESCOVY for HIV-1 treatment, 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 DESCOVY and become harder to treat. If you are taking DESCOVY to reduce your risk of

getting HIV, you must take DESCovy every day to protect yourself from getting HIV-1.

If you use too much DESCovy

If you think that you have used too much DESCovy, 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 DESCovy?

Things you should do

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

Things you should not do

- Do not stop using this medicine suddenly.
- **Do not breastfeed.**
- **Avoid doing things that can spread HIV infection since DESCovy does not stop you from passing the HIV infection to others.**
 - **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 DESCovy if the packaging is torn or shows signs of tampering.**

If you are taking DESCovy to reduce your risk of getting HIV

You must stay HIV-negative to keep taking DESCovy.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how DESCovy 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 DESCovy tablets in the bottle with the cap tightly closed until you take them.
- Keep DESCovy 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.

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">• nausea• diarrhea• fatigue• headaches• abdominal pain• indigestion• flatulence• rash• vomiting• abnormal dreams	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
<p><u>Serious Liver Problems (hepatotoxicity)</u></p> <ul style="list-style-type: none"> • 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 <p>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.</p> <p><u>Hepatic Flares</u></p> <p>If you have HBV infection you should not stop your DESCOVY treatment without first discussing this with your doctor. Your HBV may get worse (flare-up) if you stop taking DESCOVY. 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. You must discuss your HBV therapy with your doctor.</p> <p><u>Signs and symptoms of inflammation</u></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 been present with no obvious symptoms. If you notice any symptoms of infection, please tell</p>	<p>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.</p>

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.

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 DESCOVY 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.

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 DESCOVY contains

Active ingredient (main ingredient)	emtricitabine tenofovir alafenamide
Other ingredients (inactive ingredients)	microcrystalline cellulose croscarmellose sodium magnesium stearate <u>Film-coating (200/25 mg tablets)</u> polyvinyl alcohol titanium dioxide polyethylene glycol talc indigo carmine aluminum lake <u>Film-coating (200/10 mg tablets)</u> polyvinyl alcohol titanium dioxide polyethylene glycol talc iron oxide black
Potential allergens	N/A

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

What DESCOVY looks like

The 200/25 mg DESCOVY tablets are rectangular-shaped, film-coated and blue in colour.

Each tablet is debossed with "GSI" on one side and the number "225" on the other side.

The 200/10 mg DESCOVY tablets are rectangular-shaped, film-coated and gray in colour.

Each tablet is debossed with "GSI" on one side and the number "210" on the other side

DESCOVY tablets are supplied in bottles containing 30 tablets.

DESCOVY 200/10 mg tablets AUST R 246093

DESCOVY 200/25 mg tablets AUST R 246092

Who distributes DESCOVY

Australia

Gilead Sciences Pty Ltd

Level 6, 417 St Kilda Road

Melbourne, Victoria 3004

New Zealand

c/- Grant Thornton New Zealand Limited,

L4, 152 Fanshawe Street

Auckland 1010

This leaflet was prepared in June 2022.

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