

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 VIREAD?

VIREAD contains the active ingredient tenofovir disoproxil fumarate. VIREAD is used to treat two different viruses: chronic hepatitis B (CHB) and Human Immunodeficiency Virus-1 (HIV-1) infection.

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

2. What should I know before I use VIREAD?

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

3. What if I am taking other medicines?

Some medicines may interfere with VIREAD 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 VIREAD?

- The usual dose is one VIREAD tablet orally, once daily.
- VIREAD is best taken with a meal or just afterwards, however taking it without food should not reduce the effectiveness of the medicine.
- If you are taking VIREAD to treat HIV or if you have HIV and hepatitis B virus coinfection, always take VIREAD in combination with other anti-HIV medicines.

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

5. What should I know while using VIREAD?

Things you should do	<ul style="list-style-type: none"> • Remind any doctor, dentist or pharmacist you visit that you are using VIREAD. • Tell your doctor if you become pregnant or are trying to become pregnant
Things you should not do	<ul style="list-style-type: none"> • Do not stop using this medicine suddenly. • Do not breastfeed.
Driving or using machines	<ul style="list-style-type: none"> • Be careful driving or operating machinery until you know how VIREAD affects you.
Looking after your medicine	<ul style="list-style-type: none"> • Keep your VIREAD tablets in the bottle with the cap tightly closed until you take them. • Keep VIREAD tablets in a cool, dry place where it stays below 25 °C.

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

6. Are there any side effects?

Common side effects include diarrhoea, dizziness, nausea, and vomiting.

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.

Consumer Medicine Information (CMI)

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

Where to find information in this leaflet:

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

1. Why am I using VIREAD?

VIREAD contains the active ingredient tenofovir disoproxil fumarate.

VIREAD is an antiviral medication used to treat two different viruses; Chronic Hepatitis B (CHB) and Human Immunodeficiency Virus (HIV) infection.

VIREAD is a type of medicine called a HBV polymerase inhibitor and a nucleotide analog reverse transcriptase inhibitor (NRTI).

Chronic Hepatitis B

VIREAD is used to treat CHB (an infection with hepatitis B virus [HBV]) in adults and paediatric patients aged 12 years and older and weighing at least 35 kg.

VIREAD works by interfering with the normal working of enzymes (HBV DNA polymerase) that are essential for HBV to reproduce itself. VIREAD may help lower the amount of hepatitis B virus in your body by lowering the ability of the virus to multiply and infect new liver cells and can improve the inflammation and scar tissue caused by the hepatitis B virus in your liver. Lowering the amount of virus in your body may reduce the chance of developing cirrhosis, liver failure and liver cancer.

We do not know how long VIREAD may help treat your hepatitis. Sometimes viruses change in your body and medicines no longer work. This is called drug resistance.

HIV-Infection

VIREAD is also used to treat HIV infection in adults and paediatric patients aged 12 years and older and weighing at least 35 kg. VIREAD is always used in combination with other anti-HIV medicines to treat people with HIV-1 infection.

HIV infection destroys CD4 (T) cells, which are important to the immune system. After a large number of T cells are destroyed, acquired immune deficiency syndrome (AIDS) develops.

VIREAD helps to block HIV-1 reverse transcriptase, a chemical (enzyme) in your body that is needed for HIV-1 to multiply. VIREAD lowers the amount of HIV 1 in the blood (called viral load) and may help to increase the number of T cells (called CD4 cells). Lowering the amount of HIV-1 in the blood lowers the chance of death or infections that happen when your immune system is weak (opportunistic infections).

You do not have to have HIV-infection to be treated with VIREAD for HBV and vice versa.

2. What should I know before I use VIREAD?

Warnings

Always check the ingredients to make sure you can use this medicine.

Do not use VIREAD if:

- you are allergic to any of the ingredients listed at the end of this leaflet.
- you are already taking any other medicines that contain the same active ingredient.
- you are also taking adefovir dipivoxil to treat your hepatitis B virus (HBV) infection.
- you are already taking tenofovir alafenamide to treat HIV or 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:

- have kidney problems
- have bone problems
- liver problems, including hepatitis B or C virus infection
- have HIV 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

Tell your doctor if you are pregnant, or trying to become pregnant.

The effects of VIREAD on pregnant women or their unborn babies are not known.

Tell your doctor if you are breast-feeding.

Do not breast-feed if you are taking VIREAD. The active substance in this medicine (tenofovir disoproxil fumarate) has been found in breast milk at low concentrations.

Do not breast-feed if you have HIV or HBV.

If you are a woman who has or will have a baby, talk with your doctor or pharmacist about the best way to feed your baby. If your baby does not already have HIV or HBV, there is a chance that the baby can get HIV or HBV through breast-feeding.

Use in Children

VIREAD is for adults and paediatric patients aged 12 years and older and weighing at least 35 kg.

Does VIREAD cure HIV or AIDS?

VIREAD does not cure HIV infection or AIDS.

The long-term effects of VIREAD are not known at this time. People taking VIREAD may still get opportunistic infections or other conditions that happen with HIV-1 infection. Opportunistic infections are infections that develop because the immune system is weak. Some of these conditions are:

- pneumonia,
- herpes virus infections, and
- *Mycobacterium avium complex* (MAC) infection.

Does VIREAD reduce the risk of passing HIV-1 or HBV to others?

VIREAD does not reduce the risk of passing HIV-1 or HBV to others through sexual contact or blood contamination.

Continue to practice safe sex and do not use or share dirty 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 are taking:

- **VOSEVI (sofosbuvir/velpatasvir/ voxilaprevir), HARVONI (ledipasvir/sofosbuvir) or EPCLUSA (sofosbuvir/ velpatasvir) to treat your HCV infection.** These medicines may increase the amount of VIREAD in your blood, which could result in additional or more intense side effects (see SIDE EFFECTS).
- **VIDEX, VIDEX EC (didanosine);** VIREAD may increase the amount of VIDEX in your blood. You may need to be followed more carefully if you are taking VIDEX and VIREAD together. If you are taking VIDEX and VIREAD together, your doctor may need to reduce your dose of VIDEX

- **REYATAZ (atazanavir sulfate) or KALETRA (lopinavir/ritonavir);** These medicines may increase the amount of VIREAD in your blood, which could result in more side effects (see SIDE EFFECTS). You may need to be followed more carefully if you are taking VIREAD and REYATAZ or KALETRA together. VIREAD may decrease the amount of REYATAZ in your blood. If you are taking VIREAD and REYATAZ together you should also be taking NORVIR (ritonavir).

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

Your doctor may change your other medicines or change their doses.

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 VIREAD 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 VIREAD.

4. How do I use VIREAD?

How much to take

- **Take one VIREAD tablet orally once daily or as advised by your doctor.**
- If you have kidney problems, your doctor may recommend that you take VIREAD less frequently.

How to take it

- VIREAD is best taken with a meal or just afterwards, however taking it without food should not reduce the effectiveness of the medicine.
- Take VIREAD exactly as prescribed.
- Only take medicine that has been prescribed specifically for you.
- Do not give VIREAD to others or take medicine prescribed for someone else.
- **If you are taking VIREAD to treat HIV or if you have HIV and HBV coinfection and are taking VIREAD, always take VIREAD in combination with other anti-HIV medicines.** VIREAD and other medicines like VIREAD, may be less likely to work in the future if you are not taking VIREAD with other anti-HIV medicines because you may develop resistance to those medicines. If you have any questions about what medicines you should or should not be taking, please see your doctor or pharmacist.

If you have been given VIREAD to treat CHB, you are advised to get a HIV test before you start taking VIREAD and at any time after that when there is a chance you were exposed to HIV.

- **When your VIREAD supply starts to run low, get more from your doctor or pharmacist.** 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 VIREAD, and may become harder to treat. If you are taking VIREAD to treat CHB, stopping treatment may result in very severe hepatitis and serious liver problems (see SIDE EFFECTS).

If you are not sure how much VIREAD you should take, check with your doctor or pharmacist. Do not change the amount of VIREAD you take unless told to do so by your doctor.

Your doctor will tell you how much VIREAD to take and how often to take it. You will also find this information on the label of your medicine container.

Do not stop taking VIREAD without first talking to your doctor. Tell your doctor if for any reason you have not taken your medicine exactly as prescribed.

If you forget to use VIREAD

It is important to take the prescribed daily dose in order to get the maximum benefit of treatment.

If you forget to take your daily dose of VIREAD, take it as soon as you remember that day, and then go back to taking your medicine as you would normally.

If it is almost time for your next dose, 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 dose.

If you use too much VIREAD

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

Things you should do

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

Stay under a doctor's care when taking VIREAD.

Things you should not do

- Do not stop using this medicine suddenly. It is extremely important that you do not change or stop taking your medicine without first talking with your doctor or pharmacist.
- Do not breastfeed.
- Do not give this medicine to anyone else even if their symptoms seem similar to yours.
- **Do not take VIREAD if the packaging is torn or shows signs of tampering.**

Driving or using machines

Be careful before you drive or use any machines until you know how VIREAD affects you.

Some patients taking VIREAD have experienced dizziness. Make sure you know how you react to VIREAD before you drive a car, operate machinery or do anything else that could be dangerous if you are dizzy

Looking after your medicine

- Keep your VIREAD tablets in the bottle with the cap tightly closed until you take them.
- Keep VIREAD tablets in a cool, dry place where it stays below 25 °C.

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. A locked cupboard at least one-and-a-half metres above the ground is a good place to store them.

If you take VIREAD tablets out of their pack they may not keep 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 take VIREAD 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.

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 • diarrhoea • vomiting • dizziness • flatulence (intestinal gas) • low blood phosphate • shortness of breath • increased liver enzymes • increased amylase • inflammation of the liver • stomach pain • inflammation of the pancreas • rash • weakness <p>Kidney problems Some patients treated with VIREAD have had kidney problems. If you have had kidney problems in the past or need to take another drug that can cause kidney problems, your doctor may need to perform additional blood tests. Kidney problems may be associated with muscle problems and softening of the bones.</p> <p>Changes in Bone Mineral Density Laboratory tests show changes in the bones of patients treated with VIREAD. It is not known whether long-term use of VIREAD will cause damage to your bones. If you have had bone problems in the past, your doctor may need to perform additional tests or may suggest additional medication.</p>	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>
---	---

<p>effects are very rare.</p> <p><u>Lactic Acidosis</u></p> <ul style="list-style-type: none"> • 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 <p>These side effects may be due to a condition called lactic acidosis (build-up of an acid in the blood).</p> <p>Lactic acidosis can be a medical emergency and may need to be treated in the hospital.</p> <p><u>Hepatic Flares</u></p> <p>If you have hepatitis B infection or HIV and HBV infection together, you should not stop your VIREAD treatment without first discussing this with your doctor. Your HBV may get worse (flare-up) if you stop taking VIREAD. A “flare-up” or “hepatic flare” is when your HBV infection suddenly returns in a worse way than before. This flare-up may lead to liver failure and possibly liver transplantation or death.</p> <p>After stopping VIREAD, tell your doctor immediately about any new, unusual, or worsening symptoms that you notice after stopping treatment. After you stop taking VIREAD, your doctor will still need to check your health and take blood tests to check your liver for several months.</p>	
---	--

Serious side effects

Serious side effects	What to do
<p><u>Allergy</u></p> <p>Signs of allergic reaction such as:</p> <ul style="list-style-type: none"> • 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 <p>If you have any of the following symptoms soon after taking your medicine, DO NOT TAKE ANY MORE VIREAD and tell your doctor IMMEDIATELY or go to the accident and emergency department at your nearest hospital. All of these side</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>

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 VIREAD contains

Active ingredient (main ingredient)	Tenofovir disoproxil fumarate
Other ingredients (inactive ingredients)	croscarmellose sodium lactose magnesium stearate microcrystalline cellulose pregelatinised maize starch <u>Film-coating:</u> triacetin hypromellose indigo carmine aluminium lake (E132) lactose titanium dioxide (E171)
Potential allergens	N/A

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

What VIREAD looks like

VIREAD tablets are almond-shaped and blue in colour.

The tablet is debossed (indented) on one side with the word "GILEAD" and "4331" and on the other side with "300".

VIREAD tablets are supplied in bottles containing 30 tablets.

AUST R 90370

Who distributes VIREAD

Australia

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

This leaflet was prepared in December 2025.

VIREAD, VOSEVI, HARVONI and EPCLUSA are registered trademark of Gilead Sciences, Inc. Other brands listed are trademarks of their respective owners and are not trademarks of Gilead Sciences, Inc.