

1.3.2 PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

VIREAD 300 mg film-coated tablets

Tenofovir disoproxil fumarate

Lactose monohydrate 165,84 mg

Read all of this leaflet carefully before you start taking/using/are given VIREAD

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.

VIREAD has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What VIREAD is and what it is used for
2. What you need to know before you take/use VIREAD
3. How to take VIREAD
4. Possible side effects
5. How to store VIREAD
6. Contents of the pack and other information

1. What VIREAD is and what it is used for

VIREAD is a type of medicine called an HIV-1 (human immunodeficiency virus-1) nucleotide analogue reverse transcriptase inhibitor (NRTI).

1. VIREAD is always used in combination with other anti-HIV medicines to treat adults and adolescents ≥ 12 years of age weighing ≥ 35 kg with HIV-1 infection.
2. VIREAD is used in the treatment of chronic (long-lasting) hepatitis (liver infection) B virus (HBV) in adults and adolescents ≥ 12 years of age weighing ≥ 35 kg.

2. What you need to know before you take VIREAD

Do not take VIREAD:

- If you are hypersensitive (allergic) to tenofovir or any of the other ingredients of VIREAD (listed in section 6).
- If you suffer from lactose intolerance, you should avoid this product as it contains lactose monohydrate.
- If you have kidney problems or are on dialysis.
- If you are already taking emtricitabine/tenofovir disoproxil fumarate co-formulation because VIREAD contains one of the active ingredients in these medicines.
- If you are already taking other medicines containing tenofovir.
- If you are taking medicines containing adefovir dipivoxil.
- If you are breastfeeding your baby.
- If you are pregnant (see Pregnancy, breastfeeding and fertility below).

Warnings and precautions

Take special care with VIREAD:

- VIREAD does not cure HIV-1 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, Mycobacterium avium complex (MAC) infections and Mycobacterium tuberculosis.

- VIREAD does not reduce the risk of passing HIV-1 to others through sexual contact or blood contamination. Continue to practice safe sex and do not use or share needles.
- Talk to your doctor about taking an HIV test before starting treatment with VIREAD for chronic hepatitis B. You should also get a test for HBV if you are taking VIREAD for treatment of HIV.
- If you have bone problems.
- If you have liver problems, including Hepatitis B Virus infection.
- If you have kidney problems, your doctor may recommend that you not take VIREAD. Your doctor may need to monitor your kidney function while you are taking VIREAD.
- If you are taking other medicines, as VIREAD may interact with these other medicines.

You should read the professional information or patient information leaflet of the other HIV medicines that you will be taking in combination with VIREAD.

Adolescents

- It is not known if VIREAD is safe and effective in patients with HIV-1 infection who are under 12 years of age.
- It is not known if VIREAD is safe and effective in the treatment of chronic hepatitis B in patients who are under 12 years of age.

Other medicines and VIREAD

Always tell your healthcare provider if you are taking any other medicine (this includes complementary or traditional medicines).

Tell your doctor if you are taking any of the following:

- Emtricitabine / tenofovir disoproxil fumarate co-formulation. VIREAD contains one of the active ingredients in these products.
- Medicines containing tenofovir.
- Medicines containing adefovir dipivoxil.
- Didanosine. VIREAD may increase the amount of didanosine in your blood. Your doctor may need to monitor your condition more carefully if you are taking these two medicines together. If you are taking didanosine and VIREAD together, your doctor may need to reduce your dose of didanosine.
- Atazanavir or lopinavir and ritonavir co-formulation. These medicines may increase the amount of VIREAD in your blood, which could result in more side effects. Your doctor may need to monitor your condition more carefully if you are taking VIREAD and atazanavir or lopinavir and ritonavir co-formulation together. VIREAD may decrease the amount of atazanavir in your blood. If you take VIREAD and atazanavir together, you should also be taking ritonavir.
- Non-steroidal anti-inflammatory medicines (NSAIDs). When these medicines are used at a high dose or many NSAIDs are used together, there is a risk of renal failure when used with VIREAD. Speak to your healthcare provider on alternative medicines that may be used. Examples of this medicines include diclofenac and ibuprofen.
- Ledipasvir and sofosbuvir or sofosbuvir and velpatasvir, or sofosbuvir/velpatasvir/voxilaprevir co-formulation or adefovir dipivoxil. These medicines are used for a liver diseases—hepatitis C or B may increase the amount of tenofovir DF (a component of VIREAD) in your blood, which could result in increased side effects.

Keep a complete list of all the medicines that you take. Make a new list when medicines are

added or stopped. Give copies of this list to all of your healthcare providers and pharmacist every time you visit your healthcare provider or fill a prescription.

If you are taking medicines on a regular basis, concomitant use of the medicine may cause undesirable interactions. Please consult your doctor, pharmacist or other healthcare professional for advice.

VIREAD with food and drink

VIREAD may be taken with or without a meal.

Pregnancy, breastfeeding and fertility

VIREAD should not be used during pregnancy and breastfeeding.

Pregnancy

- A reliable method of contraception should be used to avoid pregnancy whilst taking VIREAD.
- Do not breastfeed if you are taking VIREAD, because your baby may experience serious side effects.
- Do not breastfeed if you have HIV. If you are a woman who has or will have a baby, talk to your doctor about the best way to feed your baby. If your baby does not already have HIV, there is a chance that the baby can get HIV through breastfeeding.
- If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before taking this medicine.

Driving and using machines

Since adverse reactions such as dizziness have been reported in patients receiving VIREAD, you should not drive, use machinery or perform any tasks that require concentration, until you are certain that VIREAD does not adversely affect your ability to do so (see section 4).

VIREAD contains lactose monohydrate

VIREAD contains lactose. If you have the rare hereditary conditions of lactose/fructose or galactose intolerance you should not take VIREAD.

If you have been told by your doctor that you have an intolerance to some sugars contact your doctor before taking this medicine.

3. How to take VIREAD

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

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

HIV infection:

Adults: The usual dose is 300 mg taken once daily, with or without food, in combination with other anti-HIV medicines.

If you are an adult with kidney problems, your doctor or healthcare provider may tell you to take VIREAD less often.

Adolescents (≥ 12 Years of Age and ≥ 35 kg): The usual dose is 300 mg taken once daily, with or without food, in combination with other anti-HIV medicines.

Chronic hepatitis B virus:

Adults: The usual dose is 300 mg taken once daily, with or without food.

Adolescents (≥ 12 Years of Age and ≥ 35 kg): The usual dose is 300 mg taken once daily, with or without food, in combination with other anti-HIV medicines.

The safety and efficacy (effectiveness) of VIREAD in children under 12 years of age and weighing less than 35 kg has not been established.

Your doctor will tell you how long your treatment with VIREAD will last.

Do not stop treatment unless your doctor instructs you to. When your VIREAD 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 VIREAD is stopped for even a short time. The virus may develop resistance to VIREAD and become harder to treat.

If you have the impression that the effect of VIREAD is too strong or too weak, tell your doctor or pharmacist.

If you take more VIREAD than you should

In the event of overdose, consult your doctor or pharmacist. If neither is available, seek help at the nearest hospital or poison control centre.

If you forget to take VIREAD

Take your missed dose as soon as you remember, if it is within a few hours after missing a dose.

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

4. Possible side effects

VIREAD can have side effects.

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

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

- swelling of the hands, feet, ankles, face, lips, mouth, tongue or throat, which may cause difficulty in swallowing or breathing,
- rash or itching,
- fainting.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to VIREAD. 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:

Lactic acidosis. Some people who have taken medicine like VIREAD (nucleoside analogues) have developed a serious 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.

Call your doctor right away if you experience the following signs or symptoms of 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.

Severe liver problems. Some people who have taken medicines like VIREAD have developed serious liver problems called hepatotoxicity, with liver enlargement (hepatomegaly) and fat in the liver (steatosis).

Call your doctor right away if you experience the following signs or symptoms of liver problems:

- 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.

Worsening of your Hepatitis B infection. Patients with Hepatitis B Virus who take VIREAD and then stop it, may get “flare-ups” of their hepatitis infection. A “flare-up” is when the HBV infection suddenly returns in a worse way than before.

- Kidney failure, rhabdomyolysis (abnormal muscle breakdown), osteomalacia (softening of the bones).
- Changes in your immune system (Immune Reconstitution Syndrome) can happen when an HIV-infected person starts taking HIV medicines. Your immune system may get stronger and

begin to fight infections that have been hidden in your body for a long time. Tell your healthcare provider right away if you start having any new symptoms after starting your HIV medicine.

- Dyspnoea (shortness of breath).
- Pancreatitis (inflammation of the pancreas).

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

Tell your doctor if you notice any of the following:

Frequent side effects:

- Nausea,
- rash, itching,
- diarrhoea, flatulence (gas), vomiting,
- headache, dizziness,
- pain,
- depression, difficulty falling asleep (insomnia).

Side effects with an unknown frequency

- New or worse kidney problems, including diabetes insipidus (the body is unable to regulate water), Fanconi syndrome (kidneys have difficulty absorbing electrolytes) and proteinuria (protein in the urine) can happen in some patients taking VIREAD. Your healthcare provider should do blood tests to check your kidneys before you start using VIREAD. If you have had kidney problems in the past or need to take another medicine that can cause kidney problems, your healthcare provider may need to do blood tests to check your kidneys during your treatment with VIREAD.
- Bone problems can happen in some patients taking VIREAD. Bone problems include bone

pain, softening or thinning (which may lead to fractures). Your healthcare provider may need to do additional tests to check your bones.

- Changes in body fat have been seen in some patients taking VIREAD. These changes may include increased amount of fat in the upper back and neck (“buffalo hump”), breast, and around the main part of your body (trunk). Loss of fat from the legs, arms and face may also happen. The cause and long term health effect of these conditions are not known at this time.
- Hypophosphataemia (lower-than-normal level of phosphate in the blood that may result in muscle weakness).
- Abdominal pain, increased amylase.
- Myopathy (muscle weakness).
- Asthenia (lack or loss of strength and energy), fever.

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

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to:

SAHPRA: <https://www.sahpra.org.za/health-products-vigilance/>

Aspen Pharmacare:

E-mail: Drugsafety@aspenpharma.com

Tel: 0800 118 088

By reporting side effects, you can help provide more information on the safety of VIREAD.

5. How to store VIREAD

Store all medicines out of reach of children.

Store at or below 30 °C.

Do not use if seal over bottle opening is broken or missing or if there is evidence of tampering with the blister pack.

Keep in original packaging until required for use.

Keep the bottle tightly closed.

Do not use after the expiry date stated on the label.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What VIREAD contains

The active substance is 300 mg of tenofovir disoproxil fumarate.

The other inactive ingredients are croscarmellose sodium, hydroxypropyl methylcellulose, lactose monohydrate, magnesium stearate, microcrystalline cellulose, pregelatinized starch, titanium dioxide and triacetin.

Contains sugar: Lactose monohydrate 165,84 mg

What VIREAD looks like and contents of the pack

VIREAD film-coated tablets are almond-shaped, white, and debossed with “GILEAD” and “4331” on one side.

VIREAD film-coated tablets are supplied as follows:

30 film-coated tablets are packed into high density polyethylene bottle with a white polypropylene child-resistant cap, together with a desiccant (1 gram silica gel high density polyethylene canister or sachet) and polyester fibre coil. The high density polyethylene bottles are sealed with an aluminium induction seal. The bottle is placed in an outer cardboard carton together with a leaflet.

30 film-coated tablets are packed in an aluminium blister strip with a polyvinylchloride inner lining sealed with an aluminium foil backing. The blister strips are packed into an outer cardboard carton together with a leaflet.

Not all packs and pack sizes are necessarily marketed.

Holder of Certificate of Registration

PHARMACARE LIMITED

Healthcare Park

Woodlands Drive

Woodmead 2191

Hotline: 0800 122 912 (South Africa)

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Access to the corresponding Professional Information**SAHPRA Repository of Professional Information and Patient Information Leaflets:**

<https://www.sahpra.org.za/pi-pil-repository/>

Aspen Pharmacare:

E-mail: Medinfo@aspenpharma.com

Tel: 0800 118 088

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