

PATIENT INFORMATION LEAFLET - CLEAN

SCHEDULING STATUS

S4

VIRONETO film-coated tablets

300 mg Tenofovir disoproxil fumarate (TDF) equivalent to 245 mg of

tenofovir disoproxil

Contains sugar: lactose monohydrate 153,33 mg per tablet

Read all of this leaflet carefully before you start taking VIRONETO

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- VIRONETO 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 VIRONETO is and what it is used for
2. What you need to know before you take VIRONETO
3. How to take VIRONETO
4. Possible side effects
5. How to store VIRONETO
6. Contents of the pack and other information

1. What VIRONETO is and what it is used for

VIRONETO is a type of medicine called a HIV-1 (human immunodeficiency virus-

1) nucleotide analogue reverse transcriptase inhibitor (NRTI).

1. VIRONETO is always used in combination with other anti-HIV medicines to treat adults with HIV-1 infection.

2. VIRONETO is used in the treatment of chronic (long-lasting) hepatitis (liver infection) B virus (HBV) in adults.

2. What you need to know before you take VIRONETO

Do not take VIRONETO:

- If you are hypersensitive (allergic) to tenofovir disoproxil or any of the other ingredients of VIRONETO (listed in section 6).
- If you are already taking emtricitabine/tenofovir disoproxil fumarate co-formulation because VIRONETO contains one of the active ingredients in these medicines.
- If you are pregnant or breastfeeding your baby.

Warnings and precautions

Take special care with VIRONETO:

- **VIRONETO does not cure HIV-1 infection or AIDS.** The long-term effects of VIRONETO are not known at this time. People taking VIRONETO 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*.
- VIRONETO 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 VIRONETO for chronic hepatitis B. You should also get a test for HBV if you are taking VIRONETO 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 VIRONETO. Your doctor may need to monitor your kidney function while you are taking VIRONETO.
- If you are taking other medicines, as VIRONETO may interact with these other medicines.

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

Children and adolescents

- It is not known if VIRONETO is safe and effective in children with HIV-1 infection who are under 18 years of age.
- It is not known if VIRONETO is safe and effective in the treatment of chronic hepatitis B in children who are under 18 years of age.

Other medicines and VIRONETO

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

The use of VIRONETO together with the following medicines may cause undesirable effects:

- Emtricitabine/tenofovir disoproxil fumarate co-formulation. VIRONETO contains

one of the active ingredients in these medicines.

- Didanosine. VIRONETO 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 VIRONETO 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 VIRONETO in your blood, which could result in more side effects. Your doctor may need to monitor your condition more carefully if you are taking VIRONETO and atazanavir or lopinavir and ritonavir co-formulation together. VIRONETO may decrease the amount of atazanavir in your blood. If you take VIRONETO 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 VIRONETO. Speak to your healthcare provider on alternative medicines that may be used. Examples of this medicines include diclofenac and ibuprofen.

- Medicines that may damage your kidneys. Some examples include:

- adefovir dipivoxil (for hepatitis B)
- cidofovir (for viral infection)
- acyclovir (for viral infection)
- valacyclovir (for viral infection)
- ganciclovir (for viral infection)
- valganciclovir (for viral infection)

VIRONETO with food and drink

VIRONETO may be taken with or without a meal.

Pregnancy and 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 health care provider for advice before taking this medicine.

The safety of VIRONETO during pregnancy and whilst breastfeeding has not been established. A reliable method of contraception should be used to avoid pregnancy whilst taking VIRONETO.

Do not breastfeed if you are taking VIRONETO, 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.

There is no information on fertility with VIRONETO.

Driving and using machines

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

VIRONETO contains lactose monohydrate

VIRONETO contains lactose monohydrate. Patients with the rare hereditary conditions of lactose/fructose or galactose intolerance should not take VIRONETO.

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

3. How to take VIRONETO

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

Always take VIRONETO 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 VIRONETO less often.

Chronic hepatitis B virus:

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

The safety and efficacy (effectiveness) of VIRONETO in patients younger than 18 years of age has not been established.

Your doctor will tell you how long your treatment with VIRONETO will last. Do not stop treatment unless your doctor instructs you to.

When your VIRONETO 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 VIRONETO is stopped for even a short time. The virus may develop resistance to VIRONETO and become harder to treat.

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

If you take more VIRONETO than you should

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

If you forget to take VIRONETO

Take your missed dose as soon as you remember, if it is within a few hours after missing a dose. You should not take the forgotten dose if your next dose is within 12 hours of your usual dosage time. Do not take a double dose to make up for forgotten individual doses.

4. Possible side effects

VIRONETO can have side effects.

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

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

Frequency unknown:

- 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 VIRONETO. You may need urgent medical attention or hospitalisation.

VIRONETO may cause the following **serious** side effects:

Less frequent:

Lactic acidosis. Some people who have taken medicine like VIRONETO (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 VIRONETO 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 VIRONETO 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.

Tell your doctor if you notice any of the following:

Frequent:

- hypophosphataemia (lower-than-normal level of phosphate in the blood that may result in muscle weakness);
- dizziness, inability to sleep, headache;
- diarrhoea, vomiting, nausea, stomach pain, winds;
- itching, rash;
- asthenia (lack or loss of strength and energy);
- fever;
- tiredness.

Less frequent:

- abdominal pain, increased amylase (gall bladder infection), pancreatitis (inflammation of the pancreas);
- myopathy (muscle weakness);
- new or worse kidney problems, including kidney failure can happen in some patients taking VIRONETO. Your healthcare provider should do blood tests to check your kidneys before you start using VIRONETO. 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 VIRONETO;
- Passing abnormally large amounts of urine (polyuria);
- bone problems can happen in some patients taking VIRONETO. 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 VIRONETO. 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;

- 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.

Frequency unknown:

- allergic reactions,
- dyspnoea (shortness of breath).

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 via the “**6.04 Adverse Drug Reactions & Quality Problem Reporting Form**”, found online under SAHPRA's publications:

https://sahpra.org.za/wp-content/uploads/2020/01/6.04_ARF1_v5.1_27Jan2020.pdf

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

5. How to store VIRONETO

Store all medicines out of reach of children.

- Store at or below 30 °C. protect from moisture.

- Keep in original package until required for use.
- Do not store in a bathroom
- Do not use after the expiry date stated on the label / carton / bottle

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 VIRONETO contains

- The active substance is tenofovir disoproxil fumarate. Each film-coated tablet contains 300 mg tenofovir disoproxil fumarate (TDF) equivalent to 245 mg of tenofovir disoproxil.

Contains sugar: lactose monohydrate 153,33 mg per tablet.

- The other ingredients are:

Core tablet: croscarmellose sodium, lactose monohydrate, magnesium stearate, microcrystalline cellulose, pregelatinised starch.

Film coat: hypromellose, macrogol/PEG, titanium dioxide (E171).

What VIRONETO looks like and contents of the pack

VIRONETO tablets are white circular film-coated convex tablets, engraved TDF on one side and plain on the other side.

VIRONETO tablets are packed in Al/Al cold form blisters containing 10 tablets. 3 blister cards per cardboard box; or in round, white opaque HDPE bottle, with white opaque polypropylene screw cap with induction sealed liner and containing a silica gel sachet as desiccant.

Pack size: 30 tablets.

Holder of Certificate of Registration

Strides Pharma (SA) Pty Ltd

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This leaflet was last revised in

25 April 2023

Registration number

53/20.2.8/0106

Access to the corresponding Professional Information

To be confirmed.