PART III: CONSUMER INFORMATION

Pr TENOFOVIR
Tenofovir Disoproxil Fumarate Tablets,
Manufacturer's Standard.
300 mg

This leaflet is part III of a three-part "Product Monograph" published when TENOFOVIR was approved for sale in Canada and is designed specifically for consumers. This leaflet is a summary and will not tell you everything about TENOFOVIR. Contact your healthcare professional if you have any questions about the drug.

ABOUT THIS MEDICATION

What the medication is used for:

- TENOFOVIR is a type of medicine called a nucleotide analog reverse transcriptase inhibitor (NRTI).
- Use in the Treatment of HIV-Infection:
  TENOFOVIR is a treatment for Human Immunodeficiency Virus (HIV) infection in adults and adolescents age 12 years and older and weighing at least 35 kg (77 lb). TENOFOVIR is always used in combination with other anti-HIV medicines to treat people with HIV 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.
- Use in the Treatment of Chronic Hepatitis B:
  TENOFOVIR is also used to treat chronic hepatitis B (an infection with hepatic B virus [HBV]) in adults age 18 years and older.
- If you have both HIV and HBV infection and are taking TENOFOVIR, your doctor should be prescribing TENOFOVIR in combination with other anti-HIV medicines **(See: Proper Use of This Medication)**.

What it does:

Treatment of HIV infection:

- In patients with HIV infection, TENOFOVIR helps to block HIV reverse transcriptase (enzyme) that is needed for HIV to multiply. TENOFOVIR lowers the amount of HIV in the blood (called viral load).
- TENOFOVIR does not cure HIV infection or AIDS. The long-term effects of TENOFOVIR are not known at this time. People taking TENOFOVIR may still get opportunistic infections or other conditions that happen with HIV infection. Opportunistic infections are infections that develop because the immune system is weak.

Treatment of Chronic Hepatitis B:

- In patients with HBV infection, TENOFOVIR works by interfering with the normal working of enzymes (HBV DNA polymerase) that are essential for the HBV virus to reproduce itself. TENOFOVIR 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.
- We do not know how long TENOFOVIR may help your hepatitis. Sometimes viruses change in your body and medicines no longer work. This is called drug resistance.

TENOFOVIR does not reduce the risk of passing HIV or HBV to others through sexual contact or blood contamination. Continue to practice safe sex and do not use or share dirty needles.

When it should not be used:

- Do not take TENOFOVIR if you are allergic to TENOFOVIR or any of its ingredients **(See: What the important nonmedicinal ingredients are)**.
- Do not take TENOFOVIR if you are already taking TRUVADA®, ATRIPLA®, or COMPLERA®, or STRIBILD® because TENOFOVIR is one of the active ingredients in these products.
- Do not take TENOFOVIR if you have not already discontinued treatment with HEPSERA®.

What the medicinal ingredient is:
Tenofovir disoproxil fumarate (TDF)

What the nonmedicinal ingredients are:
Croscarmellose sodium, lactose monohydrate, magnesium stearate and microcrystalline cellulose. The film coating contains: FD&C Blue #2, hypromellose, lactose monohydrate, titanium dioxide and triacetin.

What dosage forms it comes in:
TENOFOVIR is available as tablets.

Each tablet contains 300 mg of tenofovir DF, which is equivalent to 245 mg of tenofovir disoproxil. TENOFOVIR 300 mg tablets are light blue film-coated, almond shaped, biconvex tablets debossed with "M" on one side of the tablet and 'TN300' on the other side.

WARNINGS AND PRECAUTIONS

Serious Warnings and Precautions

- The most serious possible side effect is harm to the kidneys, including damage to kidney cells, kidney tissue inflammation and kidney failure. Your healthcare professional may monitor your kidney function before beginning and while receiving TENOFOVIR. Some patients treated with TDF (a component of TENOFOVIR) have had kidney problems. Your doctor may need to perform additional blood tests if you have had kidney problems in the past or need to take another drug that can cause kidney problems.

- **If you have Hepatitis B Virus infection or if you have HIV and HBV infection together, "flare-ups" of Hepatitis B Virus infection,** in which the disease suddenly returns in a worse way than before, can occur if you stop taking TENOFOVIR. Do not stop taking TENOFOVIR without your healthcare professional's advice. If you stop taking TENOFOVIR, tell your healthcare professional immediately about any new, unusual or worsening symptoms that you notice after stopping treatment. After you stop taking TENOFOVIR, your healthcare professional will still need to check your health and take blood tests to check your liver for several months.

- The class of medicines to which TENOFOVIR belong (NRTIs) can cause a condition called lactic acidosis (build up of acid in the blood). The symptoms that may be signs of lactic acidosis include: feeling very weak, tired or uncomfortable, unusual or unexpected stomach discomfort, feeling cold, feeling dizzy or lightheaded, suddenly developing a slow or irregular heart beat. This rare but serious side effect has occasionally been fatal.

- Severe liver problems can happen in people who take TENOFOVIR or similar medicines. You may develop an enlarged liver (hepatomegaly) or a fatty liver (steatosis). Non-specific symptoms such as yellowing of the skin and eyes, nausea, vomiting, and stomach pain might indicate the development of liver problems.

  Lactic acidosis or severe liver problems occur more often in women, particularly if they are very overweight. You should consult your healthcare professional immediately if such symptoms occur while you are receiving TENOFOVIR. If you notice these symptoms, stop taking TENOFOVIR and consult a healthcare professional immediately.

- TDF caused harm to the bones of animals. TDF reduced bone density in humans. If you notice bone pain, suffer a bone fracture, or other bone problem, consult your healthcare professional. If you have bone problems, you may wish to discuss calcium and/or vitamin D supplements with your healthcare professionals.

- Do not take TENOFOVIR if you are already taking ATRIPLA®, COMPLERA®, DESCOVY®, GENVOYA®,ODEFSEY™, STRIBILD®, TRUVADA® or VEMLIDY™ because these medicines contain the same or similar active ingredients.
- Do not take TENOFOVIR if you have not already discontinued treatment with HEPSERA®.

BEFORE you use TENOFOVIR talk to your healthcare professional if:

- ***You are pregnant or planning to become pregnant:*** Pregnant mothers should not take TENOFOVIR unless specifically directed by the healthcare professional. If you take TENOFOVIR while you are pregnant, talk to your doctor about how you can be included in the Antiviral Pregnancy Registry.

- ***You are breastfeeding or planning to breastfeed:*** Do not breastfeed if you are taking TENOFOVIR. Tenofovir passes to your baby in your breast milk. You should not breastfeed because of the risk of passing HIV or HBV to your baby. Talk to your healthcare professional about the best way to feed your baby.

- ***You have other medical conditions:*** Let your healthcare professional know if you have other medical conditions, especially hepatitis (inflammation of the liver), pancreatitis (inflammation of the pancreas), and bone and kidney problems.

- ***You have HIV Infection.***

- ***You are taking other medicines:*** Some medicines can interact when taken together, including prescription and non-prescription medicines and dietary supplements.

Other Special Warnings:

Your blood sugar levels (glucose) or levels of fats (lipids) in your blood may increase with HIV treatment. Your doctor may order blood tests for you.

INTERACTIONS WITH THIS MEDICATION

- Drugs that contain didanosine (Videx®, Videx EC®). TDF (TENOFOVIR) may increase the amount of Videx in your blood. **You may need to be followed more carefully if you are taking TENOFOVIR and Videx together.** Also, the dose of didanosine may need to be reduced.

- Reyataz® (atazanavir sulfate) Kaletra® (lopinavir/ritonavir). Prezista® (darunavir), HARVONI ® (ledipasvir /sofosbuvir) or EPCLUSA™ (sofosbuvir/velpatasvir), or VOSEVI™ (sofosbuvir/velpatasvir/voxilaprevir) may increase the amount of TDF (TENOFOVIR) in your blood, which could result in more side effects. You may need to be followed more carefully if you are taking TENOFOVIR together with Reyataz, Kaletra, Prezista, HARVONI, EPCLUSA or VOSEVI. TENOFOVIR may decrease the amount of Reyataz in your blood. If you are taking TENOFOVIR and Reyataz together, you should also be taking Norvir® (ritonavir).

PROPER USE OF THIS MEDICATION

Stay under a healthcare professional's care when taking TENOFOVIR. Do not change your treatment or stop treatment without first talking with your healthcare professional.

Carefully follow the directions and dosing schedule prescribed by your healthcare professional.

When your TENOFOVIR supply starts to run low, see your healthcare professional for a refill. 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 TENOFOVIR and become harder to treat.

If you are taking TENOFOVIR to treat your HIV or if you have HIV and HBV coinfection and are taking TENOFOVIR, always take TENOFOVIR in combination with other anti-HIV medicines. TENOFOVIR and other products like TENOFOVIR may be less likely to work in the future if you are not taking TENOFOVIR with other anti-HIV medicines because you may develop resistance to those medicines.

If you have HBV only (without HIV), TENOFOVIR can be prescribed as a single drug treatment for HBV.

Talk to your healthcare professional about taking an HIV test before you start treatment with TENOFOVIR for chronic hepatitis B.

Only take medicine that has been prescribed specifically for you. Do not give TENOFOVIR to others or take medicine prescribed for someone else.

Usual Adult Dose:

- The usual dose of TENOFOVIR is one 300 mg tablet orally (by mouth) once a day.
- TENOFOVIR may be taken with or without a meal.

Usual Adolescent (12 Years of Age and Older) Dose for HIV Infection:

- Body weight ≥35 kg (≥77 lb): Take one 300 mg TENOFOVIR tablet once daily orally.
- TENOFOVIR may be taken with or without a meal.

Overdosage:

In case of drug overdose, contact your healthcare professional, hospital emergency department or Regional Poison Control Centre, even if there are no symptoms.

Missed Dose:

- If you miss a dose of TENOFOVIR, take it as soon as possible and then take your next scheduled dose at its regular time.
- Do not double the next dose.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

The most common side effects of tenofovir DF are:

- Diarrhea
- Nausea
- Vomiting
- Dizziness

Other side effects include:

- Flatulence (intestinal gas)
- Allergic reaction, including angioedema (swelling of the blood vessels), with symptoms such as skin rash, redness, swelling of the hands, legs, feet, face, lips, tongue or throat with difficulty in breathing
- Stomach pain
- Weakness
- Inflammation of the pancreas
- Shortness of breath
- Headache
- Rash

Changes in your immune system (Immune Reconstitution Inflammatory Syndrome) can happen when you start 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, or you could develop an autoimmune disease in which your immune system reacts against your own body (e.g. Grave's disease (which affects the thyroid gland), Guillain-Barre syndrome (which affects the nervous system) or polymyositis (which affects the muscles) and it may develop at any time, sometimes months later after the start of HIV therapy). Sometimes symptoms can be severe, so if you develop high temperature (fever), joint or muscle pain, redness, rash, swelling or fatigue, or any new symptoms, contact your doctor right away.

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM				
	Symptoms / effect	Talk with your healthcare professional		Stop taking drug and call your health care professional
		Only if severe	In all cases	
Rare	**Effect: Kidney problems** **Symptoms** • Increased or decreased urination as well as increased thirst • Swelling of legs and feet • Feeling listless and tired		√ √ √	
Rare	**Effect: Lactic acidosis** **Symptoms** • Feeling very weak or tired • Unusual muscle pain • Stomach pain with nausea and vomiting • Feeling cold especially in arms and legs • Feeling dizzy or lightheaded • Fast or irregular heartbeat		√ √ √ √ √ √	
Very Rare	**Effect: Hepatotoxicity (severe liver problems) with hepatomegaly (liver enlargement) and steatosis (fat in the liver)** **Symptoms** • Jaundice (skin or the white part of eyes turn yellow) • Urine turns dark • Bowel movements (stools) turn light in color • Loss of appetite for several days or longer • Feeling sick to your stomach (nausea) • Lower stomach pain		√ √ √ √ √ √	
Very Rare	**Effect: Flare-ups of hepatitis B virus infection following drug discontinuation** **Symptoms** • Jaundice (skin or the white part of eyes turn yellow) • Urine turns dark • Bowel movements (stools) turn light in color • Loss of appetite for several days or longer • Feeling sick to your stomach (nausea) • Lower stomach pain		√ √ √ √ √ √	

Lactic acidosis is a medical emergency and must be treated in the hospital. You may be more likely to get lactic acidosis or serious liver problems if you are very overweight (obese) or have been taking nucleoside analog medicines, like TENOFOVIR, for a long time.

Muscle pain, muscle weakness, bone pain and softening of the bone (infrequently contributing to fractures) have also been reported.

This is not a complete list of side effects. For any unexpected side effects while taking TENOFOVIR, contact your healthcare professional.

HOW TO STORE IT

- Keep TENOFOVIR and all other medications out of reach and sight of children.
- TENOFOVIR should be stored at 15ºC –30ºC (59-86ºF). It should remain stable until the expiration date printed on the label.
- Do not keep medicine that is out of date or that you no longer need. If you throw any medicines away, make sure that children will not find them.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

If you want more information about TENOFOVIR:

- Talk to your healthcare professional.
- Find the full product monograph that is prepared for healthcare professionals and includes this Consumer Information by visiting the Health Canada website (https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html), or by contacting Sivem Pharmaceuticals ULC at: 1 855 788-3153
- . This document can be found at: www.sivem.ca.

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