

**READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE
PATIENT MEDICATION INFORMATION**

**DELSTRIGO®**

doravirine/lamivudine/tenofovir disoproxil fumarate tablets

Read this carefully before you start taking **DELSTRIGO® (doravirine/lamivudine/tenofovir disoproxil fumarate)** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **DELSTRIGO®**.

Serious Warnings and Precautions

- **Worsening of hepatitis B virus in people who have HIV-1 infection:**
If you have both HIV and hepatitis B virus infection, your hepatitis B virus infection may get worse (flare up) if you stop taking DELSTRIGO®. If you have both HIV and hepatitis B virus infection and stop taking DELSTRIGO®, talk to your doctor immediately if you have a flare up of your hepatitis B virus infection. Symptoms of a flare up can include the following: jaundice (skin or the white part of eyes turns 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. Your doctor will closely monitor your health after you stop treatment. You may require blood tests for several months after stopping treatment. DELSTRIGO® is not approved for the treatment of hepatitis B virus infection, so you must discuss your hepatitis B virus infection therapy with your doctor.
- The most serious possible side effect is harm to the kidneys, including damage to kidney cells, kidney tissue inflammation and kidney failure. Your doctor may monitor your kidney function before beginning and while receiving DELSTRIGO®. Some patients treated with tenofovir disoproxil fumarate (one of the medicines in DELSTRIGO®) 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.

What is DELSTRIGO® used for?

- DELSTRIGO® is used to treat Human Immunodeficiency Virus-1 (HIV-1) infection in adults. HIV is the virus that causes AIDS (Acquired Immune Deficiency Syndrome).
- DELSTRIGO® is for people who do not have HIV virus that is resistant to doravirine, lamivudine or tenofovir.

How does DELSTRIGO® work?

- Doravirine is a type of medicine called an HIV-1 non-nucleoside reverse transcriptase inhibitor (NNRTI).
- Lamivudine is a type of medicine called an HIV-1 nucleoside analogue reverse transcriptase inhibitor.
- Tenofovir disoproxil fumarate is a type of medicine called an HIV-1 nucleoside analogue reverse transcriptase inhibitor.
- The medicines in DELSTRIGO® block an enzyme that HIV needs in order to make more virus.
- DELSTRIGO® can help lower the amount of HIV in your blood (called your “viral load”) and increase your CD4+ T cell count which can make your immune system stronger. This may reduce your risk of death or getting infections that can happen when your immune system is weak.
- DELSTRIGO® does not cure HIV or AIDS. It is important to keep taking DELSTRIGO® to control your HIV infection.

What are the ingredients in DELSTRIGO®?

Each tablet has the following medicines: doravirine, lamivudine, and tenofovir disoproxil fumarate.

Each tablet has the following ingredients that are not medicines: Carnauba wax, colloidal silicon dioxide, croscarmellose sodium, hypromellose acetate succinate, magnesium stearate, microcrystalline cellulose and sodium stearyl fumarate.

Each tablet is covered with the following ingredients that are not medicines: Hypromellose, iron oxide yellow, lactose monohydrate, titanium dioxide, and triacetin.

DELSTRIGO® comes in the following dosage form:

As tablets containing 100 mg of doravirine, 300 mg of lamivudine, and 300 mg of tenofovir disoproxil fumarate (equivalent to 245 mg of tenofovir disoproxil).

Do not use DELSTRIGO® if you:

- are allergic to doravirine, lamivudine or tenofovir disoproxil fumarate.
- are allergic to any of the other ingredients in DELSTRIGO® or any part of the container.
- **are taking any of the following medicines:**
 - carbamazepine, oxcarbazepine, phenobarbital, phenytoin which are used to treat seizures
 - enzalutamide, used to treat prostate cancer
 - rifampin, used to treat tuberculosis
 - mitotane, used to treat cancer
 - St. John’s wort which is an herbal product used to treat depression
 - adefovir dipivoxil, used to treat hepatitis B infection.

It is not known if DELSTRIGO® is safe and effective in children under 18 years of age.

There is very little information on the combination use of doravirine, lamivudine and tenofovir disoproxil fumarate in patients 65 years of age and over.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take DELSTRIGO®. Talk about any health conditions or problems you may have, including if you:

- have hepatitis B virus infection.
- have hepatitis C virus infection.
- have kidney problems.
- have severe liver problems.
- have a history of bone fractures due to your bone problems, or are at risk for bone softening or thinning.
- have or had any allergies.
- are pregnant or planning to become pregnant.
- are breastfeeding or planning to breastfeed.
- are taking any of the following combination of medicines to treat your hepatitis C infection: ledipasvir/sofosbuvir, sofosbuvir/velpatasvir or sofosbuvir/velpatasvir/voxilaprevir.

Other warnings you should know about:

Pregnancy:

Tell your doctor if you are pregnant or planning to become pregnant. It is not known if DELSTRIGO® can harm your unborn baby. Tell your doctor if you become pregnant while you are taking DELSTRIGO®.

Pregnancy Registry:

There is a pregnancy registry for women who take antiretroviral medicines while they are pregnant. The purpose of this registry is to collect information about the health of you and your baby. If you do become pregnant while taking DELSTRIGO®, talk to your doctor about taking part in this registry.

Breastfeeding:

You should not breastfeed if you are taking DELSTRIGO®. You should also not breastfeed a baby if you are infected with HIV. This is because you can pass HIV to your baby. If you breastfeed a baby they can get HIV from you.

HIV Transmission:

DELSTRIGO® does not reduce the risk of passing HIV to others through sexual contact, sharing needles or being exposed to your blood. Always practice safe sex. Use latex or polyurethane condoms or other barrier methods to lower the chance of sexual contact with any body fluids such as semen, vaginal secretions or blood. Never re-use or share needles. Ask your doctor if you have any questions about safe sex or how to prevent passing HIV to other people.

Driving and using machines:

DELSTRIGO® may make you tired, dizzy or sleepy. This may affect your ability to drive and use machines. Before driving or using machines, wait until you are feeling well again.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

- Do not take other medicines that contain tenofovir disoproxil fumarate, tenofovir alafenamide, lamivudine, emtricitabine or adefovir dipivoxil.

The following may interact with DELSTRIGO®:

- The medicine rifabutin used to treat some bacterial infections such as tuberculosis.
 - If you also take the medicine rifabutin, take one tablet of doravirine (PIFELTRO®) about 12 hours after DELSTRIGO®, as prescribed by your doctor.
- Medicines that modify a system called CYP3A that removes medicines from your body. If you are not sure whether a medicine you take affects this system, ask your doctor.
- Medicines that reduce how well your kidney works or are removed by the kidney using the same route as DELSTRIGO® may change the blood levels of some components of DELSTRIGO®. Examples of these medicines include cidofovir, ganciclovir, vancomycin or aminoglycosides. If you are not sure if your medicine affects your kidneys or removal of medicine by the kidney, ask your doctor.

Avoid taking the following medicines with DELSTRIGO®:

- bosentan, a medicine used to treat high blood pressure in the lungs.
- dabrafenib, a medicine used to treat cancer.
- modafinil, a medicine used to treat sleep disorders.

If you cannot avoid taking these medicines with DELSTRIGO®, take one tablet of doravirine (PIFELTRO®) 12 hours after DELSTRIGO®, as prescribed by your doctor.

- Sorbitol-containing medicines (usually liquids): regular use should be avoided as these medicines can decrease blood levels of a component of DELSTRIGO®.

How to take DELSTRIGO®:

- Take DELSTRIGO® exactly as your doctor tells you.
- Your treatment with DELSTRIGO® will be initiated by a doctor with experience in the management of HIV infection.
- Do not change your dose or stop taking this or any other HIV medicine without talking to your doctor. Stay under a doctor's care when taking DELSTRIGO®.

Usual adult dose:

- Take 1 tablet once a day by mouth at about the same time every day with or without food.
- DELSTRIGO® is taken by itself (not with other HIV medicines).

Overdose:

If you think you have taken too much DELSTRIGO®, contact your healthcare professional, hospital emergency department or regional poison control centre immediately, even if there are no symptoms.

Missed Dose:

- It is important that you do not miss or skip doses of DELSTRIGO®.
- If you miss a dose, take it as soon as you remember. If you do not remember until it is almost time for your next dose, skip the missed dose and take the next dose at your regular time.
- Do not take two doses of DELSTRIGO® at the same time.
- If you are not sure what to do, call your doctor or pharmacist.

What are possible side effects from using DELSTRIGO®?

These are not all the possible side effects you may feel when taking DELSTRIGO®. If you experience any side effects not listed here, contact your healthcare professional.

The most common side effects include:

- dizziness
- abnormal dreams, difficulty in sleeping (insomnia), nightmares
- headache
- sleepiness
- feeling sick (nausea), diarrhea, vomiting
- feeling tired

Other side effects include:

- feeling weak
- depression

Serious side effects may include:

See “**Serious Warnings and Precautions box**”

Bone problems can happen in some people who take DELSTRIGO®. Bone problems include bone pain, softening, or thinning (which may lead to fractures). Your doctor may need to do additional tests to check your bones.

Immune Reconstitution Inflammatory Syndrome:

Changes to your immune system can happen when you start taking HIV-1 medicines. Your immune system may get stronger and begin to fight infections that have been hidden in your body for a long time (Immune Reconstitution Inflammatory Syndrome).

Autoimmune disorders (when the immune system attacks healthy body tissue), may also occur after you start taking medicines for HIV infection. Examples include: Grave's disease (which affects the thyroid gland), Guillain-Barré syndrome (which affects the nervous system), polymyositis (which affects the muscles), or autoimmune hepatitis (which affects the liver). Autoimmune disorders may occur many months after the start of treatment. Look for symptoms such as:

- high temperature (fever), redness, rash or swelling
- fatigue
- joint or muscle pain
- numbness or weakness beginning in the hands and feet and moving up towards the trunk of the body
- palpitations (chest pain) or rapid heart rate

If you notice these or any symptoms of inflammation or infection, tell your doctor immediately.

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
<p><u>RARE</u> Bone problems:</p> <ul style="list-style-type: none"> • bone pain • bone fracture • pain in arms or legs • muscle pain or weakness 		✓	
<p><u>RARE</u> Lactic acidosis (high level of lactic acid in the body):</p> <ul style="list-style-type: none"> • 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 heart rate 		✓	
<p><u>RARE</u> Anemia (decreased red blood cells):</p> <ul style="list-style-type: none"> • fatigue • loss of energy • shortness of breath • weakness 		✓	
<p><u>RARE</u> Kidney problems:</p> <ul style="list-style-type: none"> • increased or decreased urination as well as increased thirst • swelling of legs and feet • feeling tired • lack of energy 		✓	

<p><u>VERY RARE</u> Flare-ups of hepatitis B virus infection following drug discontinuation:</p> <ul style="list-style-type: none"> • jaundice (skin or the white part of eyes turns 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 		✓	
<p><u>VERY RARE</u> Severe allergic reactions:</p> <ul style="list-style-type: none"> • swollen face, lips, mouth, tongue or throat, which may lead to difficulty swallowing or breathing 			✓
<p><u>VERY RARE</u> Severe skin rash:</p> <ul style="list-style-type: none"> • mouth sores or blisters on your body 			✓
<p><u>VERY RARE</u> Severe Hepatomegaly with Steatosis (swollen and fatty liver):</p> <ul style="list-style-type: none"> • jaundice (skin or the white part of eyes turns yellow) • urine turns dark • bowel movements (stool) turns light in color • loss of appetite for several days or longer • feeling sick to your stomach (nausea) • lower stomach pain. 		✓	

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, talk to your healthcare professional.

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 (<http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/index-eng.php>) 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.

Storage:

Store DELSTRIGO® in the original bottle. Keep the bottle tightly closed to protect from moisture. Do not remove the desiccants.

Store DELSTRIGO® at room temperature (15°C to 30°C).

Keep out of reach and sight of children.

If you want more information about DELSTRIGO®:

- Talk to your healthcare professional.
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website (<http://hc-sc.gc.ca/index-eng.php>) or the Merck Canada website (www.merck.ca) or by calling 1-800-567-2594.

To report an adverse event related to DELSTRIGO®, please contact 1-800-567-2594.

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