Patient Medication Information

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

PIFELTRO®

doravirine tablets

This patient medication information is written for the person who will be taking **PIFELTRO® (doravirine)**. This may be you or a person you are caring for. Read this information carefully. Keep it as you may need to read it again.

This patient medication information is a summary. It will not tell you everything about this medication. If you have more questions about this medication or want more information about **PIFELTRO®**, talk to a healthcare professional.

What PIFELTRO® is used for?

- PIFELTRO® is used to treat Human Immunodeficiency Virus-1 (HIV-1) infection in adults and children 12 years of age or older who weigh at least 35 kilograms (77 pounds). HIV is the virus that causes AIDS (Acquired Immune Deficiency Syndrome).
- PIFELTRO® is used along with other medicines to treat HIV infection.
- PIFELTRO® is for people who do not have HIV virus that is resistant to doravirine.

How PIFELTRO® works?

- PIFELTRO® is a type of medicine called an HIV-1 non-nucleoside reverse transcriptase inhibitor (NNRTI).
- PIFELTRO® blocks an enzyme that HIV needs in order to make more virus.
- PIFELTRO® 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.
- PIFELTRO® does not cure HIV or AIDS. It is important to keep taking PIFELTRO® to control your HIV infection.

The ingredients in PIFELTRO® are?

Medicinal ingredient: doravirine.
Non-medicinal ingredients: Carnauba wax, colloidal silicon dioxide, croscarmellose sodium, hypromellose acetate succinate, lactose monohydrate, magnesium stearate, microcrystalline cellulose.

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

PIFELTRO® comes in the following dosage form:

As 100 mg tablets.

Do not use PIFELTRO® if you:

- are allergic to doravirine.

- are allergic to any of the other ingredients in PIFELTRO® 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

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

- are pregnant or planning to become pregnant
- are breastfeeding or planning to breastfeed
- develop a rash while taking PIFELTRO®

Other warnings you should know about:

Pregnancy:

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

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 PIFELTRO®, talk to your doctor about taking part in this registry.

Breastfeeding:

You should not breastfeed if you are taking PIFELTRO®. 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.

Driving and using machines:

PIFELTRO® 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.

The following may interact with PIFELTRO®:

- The medicine rifabutin used to treat some bacterial infections such as tuberculosis. If you also take the medicine rifabutin, take PIFELTRO® twice a day, about 12 hours apart, 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.

How to take PIFELTRO®:

- Take PIFELTRO® exactly as your doctor tells you.

- Your treatment with PIFELTRO® 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 PIFELTRO®.

Usual dose:

- Take 1 tablet once a day by mouth at about the same time every day with or without food.

Overdose:

If you think you, or a person you are caring for, have taken too much PIFELTRO®, contact a healthcare professional, hospital emergency department, regional poison control centre or Health Canada's toll-free number, 1-844 POISON-X (1-844-764-7669) immediately, even if there are no signs or symptoms.

Missed Dose:

- It is important that you do not miss or skip doses of PIFELTRO®.
- 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 PIFELTRO® at the same time.
- If you are not sure what to do, call your doctor or pharmacist.

Possible side effects from using PIFELTRO®:
These are not all the possible side effects you may have when taking PIFELTRO®. If you experience any side effects not listed here, tell your healthcare professional.

The most common side effects include:

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

Other side effects include:

- feeling weak
- depression

Serious side effects may include:

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

Frequency/Side Effect/Symptom	Talk to your healthcare professional		Stop taking this drug and get immediate medical help
	Only if severe	In all cases	
Very rare			
Allergic reactions: Severe allergic reactions causing a swollen face, lips, mouth, tongue or throat, which may lead to difficulty swallowing or breathing			✓
Unknown			
Severe skin reactions (including toxic epidermal necrolysis [TEN]): • rash • painful rash with any of the following symptoms: o fever o blisters or sores in the mouth o blisters or peeling of the skin o redness or swelling of the eyes (conjunctivitis)			✓

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell 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 (canada.ca/drug-device-reporting) 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 PIFELTRO® in the original bottle. Keep the bottle tightly closed to protect from moisture. Do not remove the desiccant.

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

Keep out of reach and sight of children.

If you want more information about PIFELTRO®:
- Talk to your healthcare professional.
- Find the full product monograph that is prepared for healthcare professionals and includes the Patient Medication Information by visiting the Health Canada Drug Product Database website (https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html); the manufacturer's website www.merck.ca, or by calling 1-800-567-2594.

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