

Patient Information
PIFELTRO® (pih-FEL-tro)
(doravirine)
tablets

What is PIFELTRO?

PIFELTRO is a prescription medicine that is used together with other HIV-1 medicines to treat Human Immunodeficiency Virus-1 (HIV-1) infection in adults and children who weigh at least 77 pounds (35 kg):

- who have not received HIV-1 medicines in the past, or
- to replace their current HIV-1 medicines for people whose healthcare provider determines that they meet certain requirements.

HIV-1 is the virus that causes Acquired Immune Deficiency Syndrome (AIDS).

It is not known if PIFELTRO is safe and effective in children who weigh less than 77 pounds (35 kg).

Who should not take PIFELTRO?

Do not take PIFELTRO if you take any of the following medicines:

- carbamazepine
- oxcarbazepine
- phenobarbital
- phenytoin
- enzalutamide
- rifampin
- rifapentine
- mitotane
- St. John's wort

Ask your healthcare provider or pharmacist if you are not sure if your medicine is one that is listed above. If you have taken any of the medicines in the past 4 weeks, talk to your healthcare provider or pharmacist before starting treatment with PIFELTRO.

What should I tell my healthcare provider before treatment with PIFELTRO?

Before treatment with PIFELTRO, tell your healthcare provider about all of your medical conditions, including if you:

- are pregnant or plan to become pregnant. It is not known if PIFELTRO can harm your unborn baby. Tell your healthcare provider if you become pregnant during treatment with PIFELTRO.
Pregnancy Registry: There is a pregnancy registry for people who take PIFELTRO during pregnancy. The purpose of this registry is to collect information about the health of you and your baby. Talk to your healthcare provider about how you can take part in this registry.
- are breastfeeding or plan to breastfeed. PIFELTRO may pass to your baby in your breast milk. Talk with your healthcare provider about the following risks to your baby from breastfeeding during treatment with PIFELTRO:
 - the HIV-1 virus may pass to your baby if your baby does not have HIV-1 infection.
 - the HIV-1 virus may become harder to treat if your baby has HIV-1 infection.
 - your baby may get side effects from PIFELTRO.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

- **Some medicines interact with PIFELTRO. Keep a list of your medicines to show your healthcare provider and pharmacist.**
- Tell your healthcare provider if you have taken rifabutin in the past 4 weeks.
- You can ask your healthcare provider or pharmacist for a list of medicines that interact with PIFELTRO.
- **Do not start taking a new medicine without telling your healthcare provider.** Your healthcare provider can tell you if it is safe to take PIFELTRO with other medicines.

How do I take PIFELTRO?

- Take PIFELTRO every day exactly as your healthcare provider tells you to take it.
- Take PIFELTRO 1 time each day, at about the same time every day.
- If you take the medicine rifabutin during treatment with PIFELTRO, take PIFELTRO 2 times each day, about 12 hours apart, as prescribed by your healthcare provider. You may not have enough doravirine in your blood if you take rifabutin during treatment with PIFELTRO.
- Take PIFELTRO with or without food.
- Do not change your dose or stop taking PIFELTRO without talking to your healthcare provider. Stay under a healthcare provider's care when taking PIFELTRO.
- It is important that you do not miss or skip doses of PIFELTRO.
- If you miss a dose of PIFELTRO, take it as soon as you remember. If it is almost time for your next dose, skip the missed dose and take the next dose at your regular time. Do not take 2 doses of PIFELTRO at the same time.
- If you have any questions, call your healthcare provider or pharmacist.
- When your PIFELTRO supply starts to run low, get more from your healthcare provider or pharmacy. 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 PIFELTRO and become harder to treat.

What are the possible side effects of PIFELTRO?

PIFELTRO can cause serious side effects, including:

- **Severe skin reactions** have happened in people treated with PIFELTRO. Call your healthcare provider right away if you develop a rash during treatment with PIFELTRO. **Stop taking PIFELTRO and get medical help right away if you develop a painful rash with any of the following symptoms:** fever, blisters or sores in the mouth, blisters or peeling of the skin, or redness or swelling of the eyes (conjunctivitis).
- **Changes in your immune system (Immune Reconstitution Syndrome)** 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. Tell your healthcare provider right away if you start having any new symptoms after starting your HIV-1 medicine.

The most common side effects of PIFELTRO include:

- nausea
- dizziness
- headache
- tiredness
- diarrhea
- stomach (abdominal) pain
- abnormal dreams

These are not all of the possible side effects of PIFELTRO.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store PIFELTRO?

- Store PIFELTRO tablets at room temperature between 68°F to 77°F (20°C to 25°C).
- Keep PIFELTRO in the original bottle.
- Do not take the tablets out of the bottle to store in another container, such as a pill box.
- Keep the bottle tightly closed to protect PIFELTRO from moisture.
- The PIFELTRO bottle contains a desiccant to help keep your medicine dry (protect it from moisture). Keep the desiccant in the bottle. **Do not eat the desiccant.**

Keep PIFELTRO and all medicines out of the reach of children.

General information about the safe and effective use of PIFELTRO.

Medicines are sometimes prescribed for purposes other than those listed in the Patient Information leaflet. Do not use PIFELTRO for a condition for which it was not prescribed. Do not give PIFELTRO to other people, even if they have the

same symptoms that you have. It may harm them. You can ask your pharmacist or healthcare provider for information about PIFELTRO that is written for healthcare professionals.

What are the ingredients in PIFELTRO?

Active ingredient: doravirine.

Inactive ingredients: colloidal silicon dioxide, croscarmellose sodium, hypromellose acetate succinate, lactose monohydrate, magnesium stearate, and microcrystalline cellulose. The tablet film coating contains hypromellose, lactose monohydrate, titanium dioxide and triacetin. The coated tablets are polished with carnauba wax.

Manufactured for: Merck Sharp & Dohme LLC
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For patent information: www.msd.com/research/patent

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For more information, go to www.PIFELTRO.com or call 1-877-888-4231.

This Patient Information has been approved by the U.S. Food and Drug Administration.

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