

IN MOMENTS OF CHANGE, WHAT KEEPS YOU GROUNDED?

Singing. I use my voice to lift others up.

Model living with HIV

WHAT IS PIFELTRO?

PIFELTRO is a prescription HIV medicine used with other antiretroviral medicines to treat human immunodeficiency virus-1 (HIV-1) infection in adults 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 AIDS (Acquired Immune Deficiency Syndrome).

Provided as an educational resource by Merck.

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Please read the accompanying <u>Patient</u> <u>Information</u> for PIFELTRO and discuss it with your healthcare provider. The physician <u>Prescribing Information</u> also is available.



IN MOMENTS OF CHANGE, WHAT KEEPS YOU GROUNDED?



READY FOR CHANGE

hange happens in life. Starting a new job, developing new relationships, or changes in your health might make you think about your priorities. If you are considering your HIV-1 treatment options, it may be time to learn about PIFELTRO.

LIFE CHANGES. STAY GROUNDED.

HHS TREATMENT GUIDELINES

The U.S. Department of Health and Human Services (HHS) guidelines support changing HIV treatment regimens for several reasons, including:



Food requirements

Potential drug-drug interactions

Tolerability/side effects

IMPORTANT SAFETY INFORMATION

Do not take PIFELTRO if you are currently taking any of the following medicines: carbamazepine, oxcarbazepine, phenobarbital, phenytoin, enzalutamide, rifampin, rifapentine, mitotane, or 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 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).



Please read the accompanying <u>Patient</u> <u>Information</u> for PIFELTRO and discuss it with your healthcare provider. The physician <u>Prescribing Information</u> also is available. ARE YOU READY FOR A CHANGE? ASK YOUR HEALTHCARE PROVIDER IF *PIFELTRO* COULD BE RIGHT FOR YOU. IN MOMENTS OF CHANGE, WHAT KEEPS YOU GROUNDED?





TAKING PIFELTRO

When change happens, forming habits can make things easier. You and your healthcare provider can decide if PIFELTRO could be right for you.

> 1 PILL taken with other HIV-1 medicines



ONCE A DAY at about the same time every day

WITH OR WITHOUT FOOD

IMPORTANT SAFETY INFORMATION (CONT'D)

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 new symptoms after starting your HIV-1 medicine.

The most common side effects of PIFELTRO include: nausea, dizziness, headache, tiredness, diarrhea, stomach (abdominal) pain, and abnormal dreams.

IMPORTANT SAFETY INFORMATION (CONT'D)

These are not all the possible side effects of PIFELTRO. For more information, ask your healthcare provider or pharmacist.

Before starting PIFELTRO, tell your healthcare provider about all 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 are breastfeeding or plan to breastfeed. PIFELTRO may pass to your baby in your breast milk. HIV may pass to your baby through your breast milk if your baby does not have HIV.

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.



Pifeltro

doravirine

Models living with HIV

PIFELTRO AND OTHER MEDICATIONS

Whether you take over-thecounter medicines, vitamins, herbal supplements, or healthcareprovider-prescribed medicines for other conditions, it is important that you talk to your healthcare provider about all of your medications.

PIFELTRO can be taken with a wide range of common, non–HIV-1 medications, such as:

Proton pump inhibitors for **heartburn** (pantoprazole)

Oral contraceptives for **birth control** (ethinyl estradiol and levonorgestrel)

Methadone for pain management

Statins for **high cholesterol** (atorvastatin)

Metformin for diabetes

IMPORTANT SAFETY INFORMATION (CONT'D)

Tell your healthcare provider if you have taken rifabutin in the past 4 weeks. **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 those other medicines.

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.

Tell your healthcare provider if you have taken rifabutin in the past 4 weeks.

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.

IN MOMENTS OF CHANGE, WHAT KEEPS YOU GROUNDED?

George. He depends on me to care for him and keep him happy.



Model living with HIV

YOUR HEALTH AND HIV-1

STAYING UNDETECTABLE IS IMPORTANT

PIFELTRO, when taken as part of a multitablet regimen, can help you get your viral load to undetectable. **Undetectable means the level of HIV in your blood is so low that lab tests can't detect it**. And when your HIV is under control, you can focus on your health and life goals beyond HIV.

IMPORTANT SAFETY INFORMATION (CONT'D)

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.

Take PIFELTRO on a regular dosing schedule as instructed by your healthcare provider. Do not miss doses.

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.

In a 48-week study, adults living with HIV-1 who were undetectable on their current treatment regimen switched to a **PIFELTRO-based single-tablet regimen** either at the start of the study, or at week 24 of the study.

AT THE START OF THE STUDY:

- 447 adults switched to a PIFELTRObased single-tablet regimen.
- 91% of those adults stayed undetectable at week 48.

AT WEEK 24 OF THE STUDY:

- **209** adults switched to a PIFELTRObased single-tablet regimen.
- **95%** of those adults were undetectable at week 24 before switching to a PIFELTRO-based single-tablet regimen.
- **95%** stayed undetectable at week 48.

AT WEEK 48 OF THE STUDY:



PIFELTRO may not have these effects on all adults living with HIV.

MORE ABOUT THIS STUDY

Participants were undetectable (HIV-1 RNA <50 copies/mL) for at least 6 months before starting the trial and had no history of resistance* to the PIFELTRO-based single-tablet regimen.

The current treatment regimens consisted of 2 nucleoside reverse transcriptase inhibitors (NRTIs) in combination with a protease inhibitor (PI) plus either ritonavir or cobicistat, elvitegravir plus cobicistat, or a nonnucleoside reverse transcriptase inhibitor (NNRTI) before switching to a PIFELTRO-based single-tablet regimen.

Participants were assigned by chance to one of the two treatment groups in the study. Participants and their healthcare providers taking part in the study knew which group they were part of.

* Resistance happens when the virus changes form and your medicine stops working.

IMPORTANT SAFETY INFORMATION (CONT'D)

Get your PIFELTRO refilled from your healthcare provider or pharmacy before you run out.

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.



Pifeltro[®] doravirine 100 mg tablets

IN MOMENTS OF CHANGE, WHAT KEEPS YOU GROUNDED?

My Grandbaby. She reminds me of what is important in life.

A LOW RATE OF SIDE EFFECTS

In a 96-week study of adults who had never been on an HIV-1 treatment before, 364 adults received a **PIFELTRO-based single-tablet regimen**, while 364 adults received an *Atripla* once-daily tablet.

Fewer adults stopped taking a PIFELTRO-based single-tablet regimen than *Atripla* because of side effects.

> Continued with A *Pifeltro*-based Single-tablet regimen

3% discontinued treatment due to side effects.

97%

VS

93% continued with Atripla (EFV/FTC/TDF).

7% discontinued treatment due to side effects.

Acronyms: EFV, efavirenz; FTC, emtricitabine; TDF, tenofovir disoproxil fumarate.

In this study, the most common side effects of a PIFELTRO-based singletablet regimen were dizziness **7%**, nausea **5%**, and abnormal dreams **5%**.

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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).

Models living with HIV

IN MOMENTS OF CHANGE, WHAT KEEPS YOU GROUNDED?

When I get anxious, he has a way of cheering me up.

> Pifeltro[®] doravirine

> > 100 mg tablets

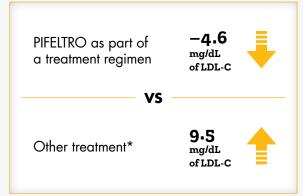
ABOUT CHOLESTEROL

HIV-1 and/or treatments for HIV may have a negative impact on your "bad" cholesterol (LDL-C).

In a 96-week study of adults who had never been on an HIV-1 treatment before, 320 adults received PIFELTRO as part of a treatment regimen and 311 adults received another treatment regimen.*

PIFELTRO, as part of a treatment regimen, did not increase "bad" cholesterol, while the other treatment regimen* did at week 48.

EFFECT ON "BAD" CHOLESTEROL (LDL-C) AT WEEK 48:



* The other treatment regimen included darunavir plus a ritonavir boost (PI + ritonavir boost), once daily.

The benefit of these changes has not been demonstrated.

IMPORTANT SAFETY INFORMATION (CONT'D)

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 new symptoms after starting your HIV-1 medicine.

The most common side effects of PIFELTRO include: nausea, dizziness, headache, tiredness, diarrhea, stomach (abdominal) pain, and abnormal dreams.

These are not all the possible side effects of PIFELTRO. For more information, ask your healthcare provider or pharmacist.

Before starting PIFELTRO, tell your healthcare provider about all your medical conditions, including if you are pregnant or plan to become pregnant. It is not known if PIFELTRO can harm your unborn baby.

IMPORTANT SAFETY INFORMATION (CONT'D)

Do not breastfeed if you take PIFELTRO. Women with HIV should not breastfeed because their babies could be infected with HIV through their breast milk.

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. 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 those other medicines.

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.

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STARTING THE CONVERSATION

Only you and your healthcare provider know what treatment is right for you. Here are some questions you can use to start a conversation with your healthcare provider about your treatment options.

- How will my treatment fit into my routine?
- What side effects could I experience?
- Can I still take other medicines with my HIV-1 medicine?
- Do I need to eat when I take my HIV-1 medicine?
- Are there other health risks my HIV-1 treatment could cause?
- Can my HIV-1 treatment raise my "bad" cholesterol?

TAKE A PIC OF THESE QUESTIONS AND DISCUSS THEM WITH YOUR HEALTHCARE PROVIDER.





LIFE CHANGES. STAY GROUNDED.

ASK YOUR HEALTHCARE PROVIDER IF PIFELTRO IS RIGHT FOR YOU.

SAVE ON YOUR OUT-OF-POCKET COSTS FOR PIFELTRO

Eligible, privately insured patients may save on their out-of-pocket costs on qualifying prescriptions for PIFELTRO. Savings are limited to amount of your out-of-pocket cost, up to a maximum program savings of \$6,800 per patient. Not all patients are eligible. Certain restrictions apply. Go to <u>PIFELTRO.com</u> to view the Terms and Conditions. ave Model living with HIV

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