

WHAT IS PIFELTRO?

PIFELTRO is a prescription medicine used together with other HIV-1 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 is the virus that causes AIDS (Acquired Immune Deficiency Syndrome).

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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.

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

DHHS TREATMENT GUIDELINES

Department of Health and Human Services (DHHS) guidelines support changing HIV-treatment regimens for several reasons, including:



Food requirements



Potential drug-drug interactions



Tolerability/side effects

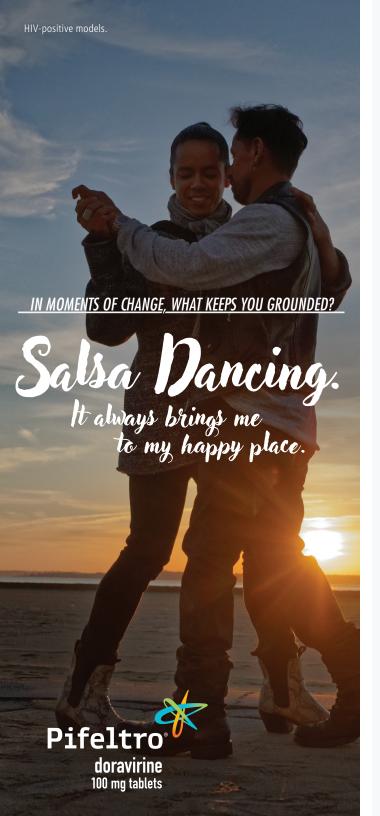
ARE YOU READY FOR A CHANGE? ASK YOUR DOCTOR IF PIFELTRO COULD BE RIGHT FOR YOU.

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 doctor 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 doctor or pharmacist before starting PIFELTRO.

Tell your doctor 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 doctor and pharmacist. Tell your doctor if you have taken rifabutin in the past 4 weeks. Do not start taking a new medicine without telling your doctor. Your doctor can tell you if it is safe to take PIFELTRO with those other medicines.





TAKING PIFELTRO

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



1 PILL As part of a complete regimen



ONCE A DAY



WITH OR WITHOUT FOOD

IMPORTANT SAFETY INFORMATION

- Take PIFELTRO every day exactly as your doctor tells you to take it.
 Take PIFELTRO 1 time each day, at about the same time every day.
- Tell your doctor 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 doctor. You may not have enough doravirine in your blood if you take rifabutin during treatment with PIFELTRO.

IMPORTANT SAFETY INFORMATION (CON'T)

- Do not change your dose or stop taking PIFELTRO without talking to your doctor. Stay under a doctor's care when taking PIFELTRO.
- Take PIFELTRO on a regular dosing schedule as instructed by your doctor. 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.
- Get your PIFELTRO refilled from your doctor or pharmacy before you run out.
- 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 AND OTHER MEDICATIONS

Whether you take over-the-counter or doctor-prescribed medicines for other conditions, it is important that you talk to your doctor about all of your medications.

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



Heartburn

PROTON PUMP INHIBITORS (pantoprazole)



Birth Control

ORAL CONTRACEPTIVES (ethinyl estradiol and levonorgestrel)



Pain

METHADONE



Cholesterol

STATINS (atorvastatin)



Diabetes

METFORMIN (metformin hydrochloride)

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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.





YOUR HEALTH AND HIV-1

PIFELTRO, when taken as part of a multi-tablet 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 (CON'T)

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 doctor and pharmacist. Tell your doctor if you have taken rifabutin in the past 4 weeks.

Do not start taking a new medicine without telling your doctor. Your doctor can tell you if it is safe to take PIFELTRO with those other medicines.

STAYING UNDETECTABLE IS IMPORTANT

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.

MORE ABOUT THIS STUDY

Patients 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 two NRTIs in combination with a PI plus either ritonavir or cobicistat, or elvitegravir plus cobicistat, or an NNRTI before switching to a PIFELTRO-based single-tablet regimen.

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

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.

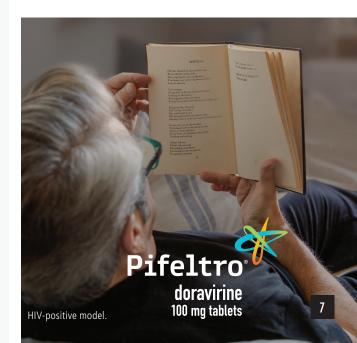
AT WEEK 48 OF THE STUDY:



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

IMPORTANT SAFETY INFORMATION (CON'T)

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



^{*} Resistance happens when the virus mutates and your medicine stops working.



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.

97%

CONTINUED WITH A PIFELTRO-BASED SINGLE-TABLET REGIMEN

3% discontinued treatment due to side effects.

VS

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

7% discontinued treatment due to side effects.

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

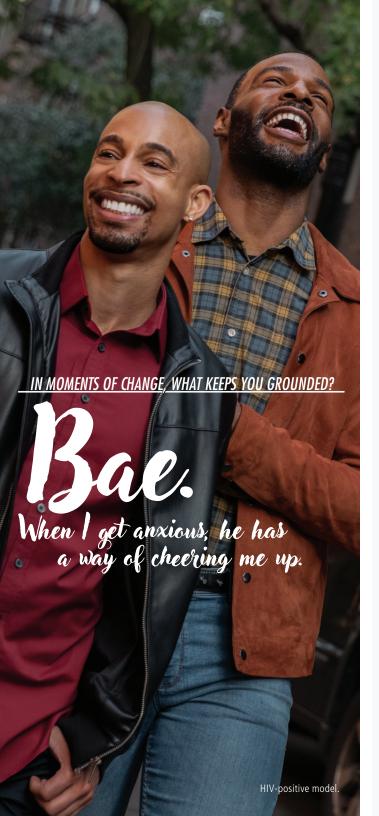
IMPORTANT SAFETY INFORMATION (CON'T)

PIFELTRO can cause serious side effects, including:

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 doctor 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 doctor or pharmacist.



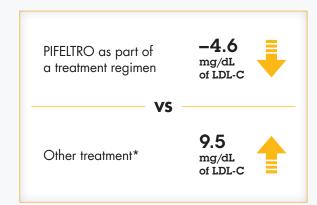
ABOUT CHOLESTEROL

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.

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

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 doctor 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 doctor or pharmacist before starting PIFELTRO.





AN ADDITIONAL TREATMENT CONSIDERATION

Maintaining a healthy weight is an important part of taking care of your health and managing your HIV. You may have concerns about weight change. If you do, talk to your doctor.

IMPORTANT SAFETY INFORMATION

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

STARTING THE CONVERSATION

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



How will my treatment fit into my routine?



What side effects could I experience?



Could my HIV-1 treatment impact my weight?



Can I still take other medications with my HIV-1 medication?



Do I need to eat when I take my HIV-1 medication?



Are there other health risks my HIV or HIV-1 treatment could cause?



TAKE A PIC OF THESE
QUESTIONS AND DISCUSS
WITH YOUR DOCTOR.





LIFE CHANGES. STAY GROUNDED.

ASK YOUR DOCTOR 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 PIFELTRO.com to view the Terms and Conditions.



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

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