doravirine (Pifeltro)

WHAT IS DORAVIRINE?

Doravirine, also known as DOR (brand name Pifeltro), is a drug used as part of antiretroviral therapy (ART). The FDA approved doravirine in 2018 as an antiretroviral drug (ARV) for people with HIV infection. Doravirine is manufactured by Merck & Co.

Doravirine is a type of drug called a non-nucleoside reverse transcriptase inhibitor (NNRTI). NNRTIs bind to and block reverse transcriptase (an HIV enzyme). HIV uses reverse transcriptase to convert its RNA into DNA (reverse transcription). Blocking reverse transcriptase and reverse transcription prevents HIV from replicating.

When used in combination with other ARVs to treat HIV infection, doravirine may help:

- Reduce the amount of HIV in your blood. This is called viral load.
- Increase the number of CD4 cells in your blood that help fight off other infections.

Reducing the amount of HIV and increasing CD4 cells in your blood may help improve your immune system. This may reduce your risk of death or getting opportunistic infections (OIs) that can happen when your immune system is weak. Read more about viral suppression.

Doravirine does not cure HIV infection or AIDS. You must keep taking HIV medicines to control HIV infection and decrease HIV-related illnesses.

WHO SHOULD TAKE DORAVIRINE?

Doravirine is a prescription HIV medicine that is used in combination with other HIV medicines to treat HIV infection in adults:

- who have not received HIV medicines in the past
  OR
- to replace their current HIV medicines when their healthcare provider determines that they meet certain requirements

The safety and effectiveness of doravirine has not been established in children under 18 years of age. Doravirine has not been carefully studied in the elderly (65 years of age and older).

All people with HIV should be on ART to keep healthy AND not transmit the virus to others. You and your healthcare provider should consider your CD4 cell count, your viral load, any symptoms you are having, and your preferences when deciding which HIV medications are right for you. Read more about U.S. ART guidelines.

WHO SHOULD NOT TAKE DORAVIRINE?

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

- Cancer medicines: enzalutamide, mitotane
- Seizure medicines: carbamazepine, oxcarbazepine, phenobarbital, phenytoin
- Tuberculosis (TB) medicines: rifampin, rifapentine
- Herbal product: St. John's Wort (*Hypericum perforatum*)

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 these medicines in the past four weeks, talk to your healthcare provider or pharmacist before starting treatment with doravirine.

WHAT SHOULD I TELL MY HEALTHCARE PROVIDER BEFORE TAKING DORAVIRINE?

Before you take doravirine, tell your healthcare provider about all of your medical conditions.

Talk to your healthcare provider if you are pregnant, you plan to become pregnant, you become pregnant, or think you may be pregnant during treatment with. It is not known if doravirine can harm your unborn baby. There is a pregnancy registry for people who take ARVs during pregnancy. The purpose of this registry is to collect information about the health of you and your baby and monitor outcomes in people exposed to ARVs during pregnancy. Talk to your healthcare provider about how you can take part in this registry. Read more about pregnancy and HIV.

Talk to your healthcare provider if you are breastfeeding or plan to breastfeed during treatment with doravirine. It is not known if

doravirine can pass to your baby in your breastmilk. You should not breastfeed if you have HIV because of the risk of passing HIV to your baby. Talk with your healthcare provider about the best way to feed your baby.

WHAT ABOUT DRUG RESISTANCE?

Many new copies of HIV are mutations. These new copies are slightly different from the original virus. Some mutations can keep multiplying even when you are taking an ARV. When this happens, the drug will stop working. This is called developing resistance to the drug. Sometimes, if your virus develops resistance to one ARV, it will also have resistance to other ARVs. This is called cross-resistance. Read more about HIV drug resistance.

Resistance can develop quickly. It is very important to take ARVs according to instructions, on schedule, and not to skip or reduce doses.

HOW IS DORAVIRINE TAKEN?

Doravirine is taken by mouth as a tablet. The recommended dosage of doravirine for adults is 100 mg once daily, in combination with other ARVs.

Doravirine can be taken with or without food.

You need to take doravirine in combination with other ARVs. Your healthcare provider will tell you what medicines to take and how to take them.

Doravirine is also available in one combination medication. Combination HIV medicines contain two or more HIV medicines from one or more drug classes.

- doravirine/lamivudine/tenofovir DF (Delstrigo)

WHAT ARE THE SIDE EFFECTS?

When you start any ARV, you may have temporary side effects such as headaches, nausea, indigestion, or a general sense of feeling ill. These side effects usually get better or disappear over time.

The most common side effects of doravirine are nausea, dizziness, headaches, tiredness, diarrhea, stomach (abdominal) pain, and abnormal dreams.

Doravirine can cause serious side effects including:

Immune Reconstitution Inflammatory Syndrome (IRIS). IRIS is a side effect that can happen when you start taking HIV medications. Your immune system might get stronger and begin to fight infections that have been hidden in your body for a long time. This may result in an inflammatory response which may require further evaluation and treatment. Tell your healthcare provider right away if you experience any new symptoms after starting doravirine.

These are not all the possible side effects of doravirine. For more information, ask your healthcare provider or pharmacist. Call your healthcare provider for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

HOW DOES DORAVIRINE REACT WITH OTHER DRUGS?

All ARVs can interact with other drugs or supplements you are taking. These interactions can change the amount of each drug in your bloodstream and cause an under- or overdose. New interactions are constantly being identified. **Tell your healthcare provider about all the medicines you take**, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Your healthcare provider can tell you if it is safe to take doravirine with other medicines.

See above for a list of medicines that should not be taken with doravirine.

MORE INFORMATION

Visit the Pifeltro website

Download the full Prescribing Information

Download the Patient Information leaflet

Download the Patient Brochure

Get a Merck coupon to help pay for your medication

Revised June 2024