Delstrigo

WHAT IS DELSTRIGO?

Delstrigo is a complete HIV regimen used as part of antiretroviral therapy (ART). Delstrigo contains three antiretroviral drugs (ARVs) combined in one tablet:

- doravirine (DOR, Pifeltro)
- lamivudine (3TC, Epivir)
- tenofovir disoproxil fumarate (tenofovir DF, TDF, Viread)

The FDA approved Delstrigo in 2018 as an ARV for people with HIV infection. Delstrigo is manufactured by Merck & Co., Inc.

One of the drugs in Delstrigo, doravirine, is a type of drug called a non-nucleoside reverse transcriptase inhibitor (NNRTI). The other two drugs, lamivudine and tenofovir DF, are nucleoside reverse transcriptase inhibitors (NRTIs). NNRTIs and NRTIs 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 alone as a complete regimen to treat HIV infection, Delstrigo 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.

Delstrigo 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 DELSTRIGO?

Delstrigo is a three-drug fixed-dose combination medication that is used alone as a complete regimen 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 Delstrigo has not been established in children under 18 years of age. Delstrigo 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.

Delstrigo provides three drugs in one pill. It can be more convenient to use Delstrigo than some other combinations of drugs that must be taken separately or at different times of the day. This could mean fewer missed doses and better control of HIV. **Delstrigo is used as a complete regimen for the treatment of HIV infection.**

WHO SHOULD NOT TAKE DELSTRIGO?

Do not take Delstrigo if you are allergic to doravirine, lamivudine, tenofovir DF, or any of the ingredients in this drug.

Do not take Delstrigo if you are taking any of the following medicines. Taking Delstrigo with these medicines may affect how Delstrigo works. Delstrigo may cause serious or life-threatening side effects or death when used with these medicines:

- Seizure medicines: carbamazepine, oxcarbazepine, phenobarbital, phenytoin
- Cancer medicines: enzalutamide, mitotane
- 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 Delstrigo.

Delstrigo is not recommended in people with severe kidney disease.

WHAT SHOULD I TELL MY HEALTHCARE PROVIDER BEFORE TAKING DELSTRIGO?

Before you take Delstrigo, tell your healthcare provider about all of your medical conditions, and in particular if you:

- Have hepatitis B virus (HBV) infection
- Have kidney problems
- Have bone problems, including a history of bone fractures

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 with Delstrigo. It is not known if Delstrigo 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 Delstrigo. Two of the drugs in Delstrigo (lamivudine and tenofovir) can pass to your baby in your breastmilk. It is not known if doravirine can pass into your breastmilk. Do 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 DELSTRIGO TAKEN?

Delstrigo is taken by mouth as a tablet. Each Delstrigo tablet contains 100 mg of doravirine, 300 mg of lamivudine, and 300 mg of tenofovir DF. The recommended dosage of Delstrigo for adults is one tablet once daily.

Take Delstrigo at the same time each day with or without food.

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 Delstrigo are dizziness, nausea, and abnormal dreams.

Delstrigo can cause serious side effects including:

Worsening of HBV infection. Your healthcare provider will test you for HBV before starting treatment with Delstrigo. If you have HBV infection and take Delstrigo, your HBV may get worse (flareup) if you stop taking Delstrigo. A flare-up is when your HBV infection suddenly returns in a worse way than before. Do not stop taking Delstrigo without first talking to your healthcare provider. Do not run out of Delstrigo. Refill your prescription or talk to your healthcare provider before your Delstrigo is all gone. If you stop taking Delstrigo, your healthcare provider will need to check your health often and do blood tests regularly for several months to check your HBV infection, or give you a medication to treat HBV. Tell your healthcare provider about any new or unusual symptoms you may have after you stop taking Delstrigo.

New or worse kidney problems, including kidney failure. Your healthcare provider should do blood and urine tests to check your kidneys before you start and during treatment with Delstrigo. Your healthcare provider may tell you to stop taking Delstrigo if you develop new or worse kidney problems during treatment with Delstrigo.

Bone problems. Bone problems include bone pain or softening or thinning of bones (which may lead to fractures). Your healthcare provider may need to do additional tests to check your bones. Tell your doctor if you have any of the following symptoms during treatment with Delstrigo:

- Bone pain that does not go away or worsening bone pain
- Pain in your arms, legs, hands, or feet
- Broken (fractured) bones
- Muscle pain or weakness

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 treatment with Delstrigo.

These are not all the possible side effects of Delstrigo. 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 DELSTRIGO 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 Delstrigo with other medicines.

See above for a list of medications that should not be taken with Delstrigo.

Delstrigo is a complete regimen for the treatment of HIV infection; therefore, taking Delstrigo with other ARVs for the treatment of HIV infection is not recommended.

MORE INFORMATION

Visit the Delstrigo website.

Visit the Delstrigo healthcare professional 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.

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