Dovato

WHAT IS DOVATO?

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

- dolutegravir (DTG, Tivicay)
- lamivudine (3TC, Epivir)

The FDA approved Dovato in 2019 as an ARV for people with HIV infection. Dovato is manufactured by ViiV Healthcare.

One of the drugs in Dovato, dolutegravir, is a type of drug called an integrase inhibitor. Integrase inhibitors block integrase (an HIV enzyme). HIV uses integrase to insert (integrate) its viral DNA into the DNA of host CD4 cells. Blocking integrase prevents HIV from replicating. The other drug, lamivudine, is a nucleoside reverse transcriptase inhibitor (NRTI). 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, Dovato 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.

Dovato 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 DOVATO?

Dovato is a two-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 Dovato has not been established in children under 18 years of age. Dovato has not been carefully studied in the elderly (65 years of age and older).

All people living 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.

Dovato provides 2 drugs in one pill. It can be more convenient to use Dovato 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. **Dovato is used as a complete regimen for the treatment of HIV infection.**

WHO SHOULD NOT TAKE DOVATO?

Do not take Dovato if you are allergic to dolutegravir, lamivudine, or any of the ingredients in this drug.

Do not take Dovato if you also take dofetilide. Taking Dovato and dofetilide can cause side effects that may be serious or life-threatening.

Dovato is not recommended in people with severe kidney or liver disease.

WHAT SHOULD I TELL MY HEALTHCARE PROVIDER BEFORE TAKING DOVATO?

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

- Have or have had liver problems, including hepatitis B virus (HBV) or hepatitis C virus (HCV) infection
- Have kidney problems

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 Dovato. One of the medicines in Dovato (dolutegravir) may harm your unborn baby. Your healthcare provider may prescribe a different medicine than Dovato if you are planning to become pregnant or if pregnancy is confirmed during the first 12 weeks of pregnancy. If you can become pregnant, your healthcare provider will perform a pregnancy test before you start treatment with Dovato and you should consistently use effective birth control (contraception) during treatment with Dovato.

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 Dovato. One of the medicines in Dovato (lamivudine) can pass to your baby in 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 DOVATO TAKEN?

Dovato is taken by mouth as a tablet. Each Dovato tablet contains 50 mg of dolutegravir and 300 mg of lamivudine. The recommended dosage of Dovato for adults is one tablet once daily.

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

If you take antacids, laxatives, or other medicines that contain aluminum, magnesium, or buffered medicines, Dovato should be taken at least 2 hours before or 6 hours after you take these medicines.

If you need to take iron or calcium supplements, including multivitamins that contain iron or calcium, by mouth during treatment with Dovato you may take these supplements at the same time that you take Dovato with food. If you do not take these supplements with Dovato and food, take Dovato at least 2 hours before or 6 hours after you take these supplements.

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 Dovato are headaches, nausea, diarrhea, trouble sleeping, tiredness, and anxiety.

Dovato can cause serious side effects, including:

Resistant HBV infection. Your healthcare provider will test you for HBV infection before you start treatment with Dovato. If you have HIV and HBV, the HBV can change (mutate) during your treatment with Dovato and become harder to treat (resistant). It is not known if Dovato is safe and effective in people who have HIV and HBV infection.

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

Allergic reactions. Call your healthcare provider right away if you develop a rash with Dovato. Stop taking Dovato and get medical help right away if you develop a rash with any of the following signs or symptoms:

- Fever
- Generally ill feeling
- Tiredness
- Muscle or joint aches
- Blisters or sores in mouth

- Blisters or peeling of the skin
- Redness or swelling of the eyes
- Swelling of the mouth, face, lips, or tongue
- Problems breathing

Liver problems. People with a history of HBV or HCV infection may have an increased risk of developing new or worsening changes in certain liver tests during treatment with Dovato. Liver problems, including liver failure, have also happened in people without a history of liver disease or other risk factors. Your healthcare provider may do blood tests to check your liver. Tell your healthcare provider right away if you get any of the following signs or symptoms of liver problems:

- Skin or the white part of your eyes turns yellow (jaundice)
- Dark or "tea-colored" urine
- Light-colored stools (bowel movements)
- Loss of appetite for several days or longer
- Nausea and vomiting
- Pain, aching, or tenderness on the right side of your stomach area

Too much lactic acid in your blood (lactic acidosis). Lactic acidosis is a serious but rare medical emergency that can cause death. Tell your healthcare provider right away if you develop any of these symptoms:

- Feel very weak or tired
- Unusual (not normal) muscle pain
- Trouble breathing
- Stomach pain with nausea or vomiting
- Cold or blue hands and feet
- Feel dizzy or lightheaded
- Have a fast or irregular heartbeat

Lactic acidosis can also lead to severe liver problems, which can lead to death. Your liver may become large (hepatomegaly) and you may develop fat in your liver (steatosis). Tell your healthcare provider right away if you get any of the signs or symptoms of liver problems which are listed above.

You may be more likely to get lactic acidosis or severe liver problems if you were assigned female at birth (AFAB) or are very overweight (obese).

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 Dovato.

These are not all the possible side effects of Dovato. 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 DOVATO 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 Dovato with other medicines.

Dovato should not be taken with dofetilide.

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

MORE INFORMATION

Visit the Dovato website.

Visit the Dovato healthcare professional website.

Download the full Prescribing Information.

Download the Patient Information leaflet.

Check out the ViiV Healthcare Patient Assistance Program.

Get a ViiV Healthcare Savings Card.

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