Cimduo

WHAT IS CIMDUO?

Cimduo is a drug used as part of antiretroviral therapy (ART). Cimduo contains two antiretroviral drugs (ARVs) combined in one tablet:

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

The FDA approved Cimduo in 2018 as an ARV for people with HIV infection. Cimduo is manufactured by Viatris.

The drugs in Cimduo, emtricitabine and tenofovir DF, are both nucleoside reverse transcriptase inhibitors (NRTIs). 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 in combination with other ARVs to treat HIV infection, Cimduo 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.

Cimduo 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 CIMDUO?

Cimduo is a prescription two-drug fixed-dose combination medication used in combination with other ARVs to treat HIV infection in adults and children weighing at least 77 pounds (35 kg). The safety and effectiveness of Cimduo has not been established in children weighing less than 77 pounds (35 kg). Cimduo 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.

Cimduo provides two drugs in one pill. It can be more convenient to use Cimduo 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. **Cimduo is used in combination with other ARVs for the treatment of HIV infection.**

WHO SHOULD NOT TAKE CIMDUO?

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

WHAT SHOULD I TELL MY HEALTHCARE PROVIDER BEFORE TAKING CIMDUO?

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

- Have liver problems, including hepatitis B virus (HBV) or hepatitis C virus (HCV) infection
- Have kidney problems, including end-stage renal disease (ESRD) that requires dialysis
- Have bone problems, including a history or 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 Cimduo. It is not known if Cimduo will 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 Cimduo. 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 CIMDUO TAKEN?

Cimduo is taken by mouth as a tablet. Each Cimduo tablet contains 300 mg of lamivudine and 300 mg of tenofovir DF. The recommended dosage of Cimduo in adults and children weighing at least 77 pounds (35 kg) is one tablet once daily.

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

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

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 Cimduo are headaches, pain, depression, diarrhea, and rash.

Cimduo can cause serious side effects including:

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

Severe liver problems. In rare cases, severe liver problems can happen that can lead to death. Tell your healthcare provider right away if you get these symptoms:

- 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 or vomiting
- Pain, aching, or tenderness on the right side of your stomach area

Worsening of HBV infection. If you have HIV and HBV infection, your HBV may get worse (flare-up) if you stop taking Cimduo. A flare-up is when your HBV infection suddenly returns in a worse way than before. Your healthcare provider will test you for HBV infection before you start treatment with Cimduo. It is not known if Cimduo is safe and effective in people who have both HIV and HBV infection. Do not run out of Cimduo. Refill your prescription or talk to your healthcare provider before your Cimduo is all gone. Do not stop Cimduo without first talking to your healthcare provider. If you stop taking Cimduo, your healthcare provider will need to check your health often and do blood tests regularly for several months to check your liver.

Worsening of HCV infection. If you have HIV and HCV infection, your HCV may get worse if you take Cimduo with interferon alfa with or without ribavirin. Tell your healthcare provider if you have any new symptoms.

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 Cimduo. Tell your healthcare provider if you get signs and symptoms of kidney problems, including bone pain that does not go away or worsening bone pain, pain in your arms, hands, legs or feet, broken (fractured) bones, muscle pain, or weakness.

Inflammation of the pancreas (pancreatitis). Children may be at risk for developing pancreatitis during treatment with Cimduo if they have taken nucleoside analogue medicines in the past, have a history of pancreatitis, or have other risk factors for pancreatitis. Call your healthcare provider right away if your child develops signs and symptoms of pancreatitis including severe upper stomach-area pain, with or without nausea and vomiting. Your healthcare provider may tell you to stop giving Cimduo to your child if their symptoms and blood test results show that your child may have pancreatitis.

Bone problems. Bone problems can happen in some people who take Cimduo. Bone problems include bone pain or softening or thinning of bones, which may lead to fractures. Your healthcare provider may need to do tests to check your bones. Tell your healthcare provider if you have any bone pain, pain in your hands or feet, or muscle pain or weakness during treatment with Cimduo.

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 Cimduo.

Changes in body fat. Changes in body fat distribution or accumulation have happened in some people taking HIV medicines, including an increased amount of fat in the upper back and neck (buffalo hump), in the breasts, and around the trunk. Loss of fat from the legs, arms, and face may also happen. The cause and long-term health effects of these body fat changes are not known.

These are not all the possible side effects of Cimduo. 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 CIMDUO 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 Cimduo with other medicines.

MORE INFORMATION

Download the full Prescribing Information.

Download the Patient Information leaflet.

Visit the Cimduo healthcare professional website.

Get a Cimduo savings card.

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