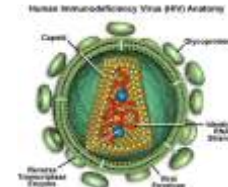
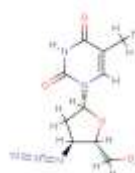


Rx LAMIVUDINE + ZIDOVUDINE

(Combivir is an oral drug that is a combination of lamivudine (EpiVir) and zidovudine (Retrovir))



GENERIC NAME: lamivudine and zidovudine

DRUG CLASS AND MECHANISM

Combivir is an oral drug that is a combination of lamivudine (EpiVir) and zidovudine (Retrovir). It is used for the treatment of infections with the human immunodeficiency virus (HIV). Lamivudine and zidovudine are in a class of drugs called reverse transcriptase inhibitors that also includes zalcitabine (Hivid) and didanosine (Videx).

During infection with HIV, the HIV virus multiplies within the body's cells. The newly-formed viruses are released from the cells and then spread throughout the body where they infect other cells. In this manner, the infection continually spreads to new, uninfected cells that the body is continually producing, and HIV infection is perpetuated. When producing new viruses, the HIV virus must manufacture new DNA for each virus. Reverse transcriptase is the enzyme that the virus uses to form this new DNA. Lamivudine and zidovudine block the activity of reverse transcriptase and block the production of DNA and new viruses. (Specifically, lamivudine is converted within the body to its active form, lamivudine triphosphate, and zidovudine is converted to its active form, zidovudine triphosphate. The active forms are similar to the naturally occurring deoxycytidine triphosphate and thymidine triphosphate, respectively, chemicals that are used by reverse transcriptase to make DNA. The reverse transcriptase uses lamivudine triphosphate and zidovudine triphosphate instead of the naturally-occurring deoxycytidine triphosphate and thymidine triphosphate for making DNA, and these active forms of the drugs interfere with the activity of reverse transcriptase.)

The effectiveness of either lamivudine or zidovudine when used alone may decrease as the HIV virus develops resistance to the effects of the individual drugs. By combining lamivudine and zidovudine, it is more difficult for the HIV virus to develop resistance to therapy since it must develop resistance to both drugs. As a result, Combivir is more effective than lamivudine or zidovudine alone. Combivir does not kill existing HIV virus, and it is not a cure for HIV. Combivir was approved by the FDA in September, 1997.

PRESCRIPTION: Yes.

PREPARATIONS: Tablets: 150/300 mg (lamivudine/zidovudine)

PRESCRIBED FOR: Combivir is used, in combination with other agents, for the treatment of HIV infection.

DOSING

For the treatment of HIV infection the recommended oral dose for adults or children greater than 12 years of age is one tablet twice daily. Combivir is administered without regard to meals since food does not affect its absorption.

DRUG INTERACTIONS

Fluconazole (Diflucan), probenecid, trimethoprim (Trimplex) and valproic acid (Depakote) reduce the elimination of zidovudine and therefore increase the blood concentration of zidovudine. This can lead to increased side effects from zidovudine.

USES

This product contains 2 drugs: lamivudine and zidovudine. It is used with other medications to help control your HIV infection, thereby improving your quality of life. It helps to decrease the amount of HIV in your body so your immune system can work better. This product also lowers your risk of getting HIV disease complications (such as new infections, cancer). Both lamivudine and zidovudine belong to a class of drugs known as nucleoside reverse transcriptase inhibitors (NRTIs). Lamivudine/zidovudine is not a cure for HIV infection and it does not prevent the spread of HIV to others through sexual contact or blood contamination (such as sharing used needles). OTHER This section contains uses of this drug that are not listed in the approved professional labeling for the drug but that may be prescribed by your health care professional. Use this drug for a condition that is listed in this section only if it has been so prescribed by your health care professional. This medication may also be used to prevent HIV infection after contact with the virus.

HOW TO USE

Read the Patient Information Leaflet if available from your pharmacist before you start taking lamivudine/zidovudine, and each time you get a refill. If you have any questions, consult your doctor or pharmacist. Take this medication by mouth with or without food, usually 2 times daily or as directed by your

doctor. Take this medication with a full glass of water (8 ounces/240 milliliters) unless your doctor directs you otherwise. Because this combination product has fixed doses of lamivudine and zidovudine, it should only be used if your doctor has determined that the doses of both medications in this product are right for you. This product is not to be used in children weighing less than 30 kilograms (66 pounds). If you are taking HIV medications for the first time, you may experience symptoms of an old infection as your immune system begins to work better. Tell your doctor immediately if you notice any trouble breathing, fever, new cough, vision problems, headaches, or skin problems. It is very important to continue taking this medication (and other HIV medications) exactly as prescribed by your doctor. Do not skip any doses. Do not increase your dose, take this drug more often than prescribed, or stop taking it (or other HIV medicines) even for a short time unless directed to do so by your doctor. Skipping or changing your dose without approval from your doctor may cause the amount of virus to increase, make the infection more difficult to treat (resistant), or worsen side effects. This medication works best when the amount of drug in your body is kept at a constant level. Therefore, take this drug at evenly spaced intervals. To help you remember, take it at the same times each day. Tell your doctor if your condition does not improve or if it worsens.

SIDE EFFECTS

See also Warning and How to Use sections. Headache, tiredness, loss of appetite, nausea, vomiting, diarrhea, trouble sleeping, dizziness, stuffy nose, or cough may occur. If any of these effects persist or worsen, tell your doctor or pharmacist promptly. Remember that your doctor has prescribed this medication because he or she has judged that the benefit to you is greater than the risk of side effects. Many people using this medication do not have serious side effects. Tell your doctor immediately if any of these unlikely but serious side effects occur: mental/mood changes (such as depression), numbness/tingling of hands/feet, signs of pancreatitis (such as nausea, vomiting, stomach/abdominal/back pain, fever), easy bruising/bleeding, skin/nail color changes. Changes in body fat may occur while you are taking this medication (such as increased fat in the upper back and stomach areas, decreased fat in the arms and legs). The cause and long-term effects of these changes are unknown. Discuss the risks and benefits of treatment with your doctor, as well as the possible use of exercise to reduce this side effect. This medication can commonly cause a rash that is usually not serious. However, you may not be able to tell it apart from a rare rash that could be a sign of a severe reaction. Therefore, seek immediate medical attention if you develop any rash. A very serious allergic reaction to this drug is unlikely, but seek immediate medical attention if it occurs. Symptoms of a serious allergic reaction may include: rash, itching/swelling (especially of the face/tongue/throat), severe dizziness, trouble breathing. This is not a complete list of possible side effects. If you notice other effects not listed above, contact your doctor or pharmacist. In the US - Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088. In Canada - Call your doctor for medical advice about side effects. You may report side effects to Health Canada at 1-866-234-2345.

PRECAUTIONS

Before taking lamivudine/zidovudine, tell your doctor or pharmacist if you are allergic to either drug; or if you have any other allergies. This product may contain inactive ingredients, which can cause allergic reactions or other problems. Talk to your pharmacist for more details. Before using this medication, tell your doctor or pharmacist your medical history, especially of: kidney problems, liver problems (such as hepatitis B or C, cirrhosis), disease of the pancreas (pancreatitis), alcohol use, low red/white blood cell counts. This drug may make you dizzy. Do not drive, use machinery, or do any activity that requires alertness until you are sure you can perform such activities safely. Limit alcoholic beverages. Also limit alcohol because it can increase the risk of liver problems and pancreatitis. Children may be more sensitive to the side effects of this drug, especially pancreatitis. Before having surgery, tell your doctor or dentist about all the products you use (including prescription drugs, nonprescription drugs, and herbal products). To decrease your risk of spreading HIV disease to others, always use an effective barrier method (latex or polyurethane condoms/dental dams) during all sexual activity. Consult your doctor or pharmacist for more details. During pregnancy, this medication should be used only when clearly needed. However, HIV medicines are now usually given to pregnant women with HIV. Treatment has been shown to decrease the risk of HIV transmission to the baby. Lamivudine/zidovudine may be part of that treatment. Discuss the risks and benefits with your doctor. Lamivudine and zidovudine pass into breast milk. Because breast milk can transmit HIV, do not breast-feed.

DRUG INTERACTIONS

The effects of some drugs can change if you take other drugs or herbal products at the same time. This can increase your risk for serious side effects or may

cause your medications not to work correctly. These drug interactions are possible, but do not always occur. Your doctor or pharmacist can often prevent or manage interactions by changing how you use your medications or by close monitoring. To help your doctor and pharmacist give you the best care, be sure to tell your doctor and pharmacist about all the products you use (including prescription drugs, nonprescription drugs, and herbal products) before starting treatment with this product. While using this product, do not start, stop, or change the dosage of any other medicines you are using without your doctor's approval. Some products that may interact with this drug include: interferon alfa, probenecid, ribavirin, stavudine, zalcitabine, drugs that may decrease bone marrow function or lower blood cell counts (such as ganciclovir, trimethoprim, cancer chemotherapy including doxorubicin), drugs that may affect the kidneys (including NSAIDs such as ibuprofen or naproxen). Other medications can affect the removal of zidovudine from your body, which may affect how lamivudine/zidovudine works. Examples include fluconazole, rifampin, valproic acid, among others. If you are also taking clarithromycin, take this medication at least 2 hours apart from your clarithromycin dose. Do not take other products that contain either lamivudine or zidovudine with this medication. Emtricitabine is similar to lamivudine and should not be taken with this medication. This document does not contain all possible interactions. Therefore, before using this product, tell your doctor or pharmacist of all the products you use. Keep a list of all your medications with you, and share the list with your doctor and pharmacist.

OVERDOSE

If overdose is suspected, contact a poison control center or emergency room immediately. US residents can call the US National Poison Hotline at 1-800-222-1222. Canada residents can call a provincial poison control center.

MISSED DOSE

If you miss a dose, take it as soon as you remember. If it is near the time of the next dose, skip the missed dose and resume your usual dosing schedule. Do not double the dose to catch up.

STORAGE

Store between 36-86 degrees F (2-30 degrees C) away from light and moisture. Do not store in the bathroom. Keep all medicines away from children and pets. Do not flush medications down the toilet or pour them into a drain unless instructed to do so. Properly discard this product when it is expired or no longer needed. Consult your pharmacist or local waste disposal company for more details about how to safely discard your product. **MEDICAL ALERT:** Your condition can cause complications in a medical emergency. For information about enrolling in MedicAlert, call 1-800-854-1166 (US) or 1-800-668-1507 (Canada).

WARNING: Zidovudine, one of the medications in this product, can decrease bone marrow function, which may lead to low numbers of red and white blood cells. A low number of red blood cells can lead to anemia. A low number of white blood cells can decrease your body's ability to fight serious, life-threatening infections. These serious side effects occur more frequently in people with advanced HIV disease (AIDS). Seek immediate medical attention if you develop any signs of anemia (such as unusual tiredness, fast breathing, pale skin, fast heartbeat) or signs of infection (such as fever, chills, cough, persistent sore throat). Your doctor will check your blood cell counts while you are taking this medication to decrease the risk of these side effects.

Zidovudine may also cause muscle problems. Seek immediate medical attention if you develop signs of muscle problems (such as wasting or decrease in muscle size, weight loss, muscle weakness/pain/tenderness).

Rarely, lamivudine and zidovudine have caused severe (sometimes fatal) liver problems and a certain metabolic problem (lactic acidosis). Tell your doctor immediately if you develop symptoms of liver problems (such as persistent nausea, vomiting, stomach/abdominal pain, pale stools, dark urine, yellowing eyes/skin, unusual tiredness), or of lactic acidosis (such as stomach discomfort, nausea, vomiting, fast/difficult breathing, drowsiness, muscle pain, weakness, cold skin). These serious side effects may occur more often in women and obese patients.

If you have hepatitis B infection and HIV, you may have a serious worsening of hepatitis symptoms if you stop taking lamivudine. Talk with your doctor before stopping this medication. Your doctor will monitor liver tests for several months after you stop lamivudine. Tell your doctor immediately if you develop symptoms of worsening liver problems.

Note : This product information is intended only for residents of the India. Taj Pharmaceuticals Limited, medicines help to treat and prevent a range of conditions—from the most common to the most challenging—for people around the world.



Taj Group of Companies ^{INDIA}

Taj Pharmaceuticals Ltd.

Phone : General EPA BX : 91 - (0)22 - 26374592/92 91,
(0)22 - 26374592/93 91 - (0)22 - 30601000,
Fax : 91-(0)22-26341274

Revised November 2010