

Rx TENOFOVIR + EMTRICITABINE

(It is used in combination with other antiviral drugs for the treatment of HIV infection)



GENERIC NAME: EMTRICITABINE/TENOFOVIR - ORAL (em-tri-SITE-ah-bean/te-NOE-fo-veer)

USES

This drug is a combination of two different antivirals, emtricitabine and tenofovir. It is used in combination with other antiviral drugs for the treatment of HIV infection. They work by slowing the growth of the virus. Emtricitabine is also called a nucleoside reverse transcriptase inhibitor, while tenofovir is also called a nucleotide reverse transcriptase inhibitor. Antiviral drugs help to control your HIV infection thereby improving your quality of life and lowering your risk of getting HIV disease complications (e.g., opportunistic infections, cancer). However, this drug is not a cure for HIV infection and it does not prevent the spread of HIV to others through sexual contact or blood contamination (e.g., sharing dirty needles).

HOW TO USE

Take this medication by mouth usually once daily with or without food; or as directed by your doctor. The dosage is based on your medical condition and response to therapy. This drug should be prescribed along with other medicines used to treat HIV. If you are also taking didanosine enteric-coated tablets, take both drugs either on an empty stomach or with a light meal. If you are taking the didanosine buffered tablets, take both drugs on an empty stomach. Continue taking this medication and other anti-HIV medications exactly as prescribed by your doctor. This medication works best when the amount of drugs in your body is kept at a constant level. Therefore, take this drug at evenly spaced intervals. Remember to use it at the same time each day. Do not take more or less of this drug than prescribed or stop taking it (or other HIV-related medicine) 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, or worsen side effects.

SIDE EFFECTS

See also Warning section. Nausea, vomiting, diarrhea, headache, dizziness, stomach upset, sweating, muscle pain, joint pain, trouble sleeping, back pain, gas or change in skin color on your palms or soles of your feet may occur. If any of these effects persist or worsen, notify your doctor or pharmacist promptly. Tell your doctor immediately if any of these serious side effects occur: loss of appetite, depression, chest pain, numbness or tingling of the hands or feet, change in the amount of urine, unusual weight loss, unusual tiredness or weakness. This medication may cause changes in your body fat (e.g., increased fat in the upper back and stomach, decreased fat in the arms and legs). The cause and long-term effects of these changes are unknown. Discuss the risks and benefits of therapy, and how exercise might reduce this side effect, with your doctor. A serious allergic reaction to this drug is unlikely, but seek immediate medical attention if it occurs. Symptoms of a serious allergic reaction include: rash, itching, swelling, severe dizziness, trouble breathing. If you notice other effects not listed above, contact your doctor or pharmacist.

PRECAUTIONS

Before taking emtricitabine/tenofovir, tell your doctor or pharmacist if you think you are allergic to it; or if you have any other allergies. This medication should not be used if you have certain medical conditions. Before using this medicine, consult your doctor or pharmacist if you have: severe kidney disease or require kidney dialysis. Before using this medication, tell your doctor or pharmacist your medical history, especially of: liver problems, kidney disease, Hepatitis B infection, bone problems, obesity. This medication should be used only when clearly needed during pregnancy. Discuss the risk and benefits with your doctor. It is not known if either drug passes into breast milk. Because breast milk can transmit HIV, do not breast-feed.

WARNING

This medication may rarely cause severe (sometimes fatal) liver and blood disorders (e.g., lactic acidosis, hepatomegaly) when used alone or with other drugs that also treat HIV. Tell your doctor immediately if you develop yellowing eyes or skin, dark urine, stomach/abdominal pain, rapid/shallow breathing, severe drowsiness, or muscle aches. If this drug is stopped, you

must continue to be closely monitored by your doctor. After the last dose of this drug, you will need your liver function tested for at least several months.

Before using this medication, tell your doctor or pharmacist of all prescription and nonprescription/herbal products you may use, especially of: certain other HIV medicines (e.g., didanosine, lopinavir/ritonavir), other antiviral medicines (e.g., acyclovir, adefovir, cidofovir, ganciclovir, lamivudine, abacavir). Tell your doctor or pharmacist if you are also using other drugs which may be harmful to the kidneys such as: aminoglycosides (e.g., gentamicin, amikacin), amphotericin B, cyclosporine, non-steroidal anti-inflammatory drugs - NSAIDS (e.g., ibuprofen), tacrolimus, vancomycin. Tenofovir can decrease the effectiveness of atazanavir (by decreasing blood levels) when you take them at the same time, which could cause your condition to worsen. If you are using both of these drugs, then you must also take ritonavir according to the manufacturer. Consult your doctor or pharmacist for more details. Check the labels on all your medicines for HIV infection because they may contain the same ingredients as found in this product. Taking too much of these drugs will not necessarily improve your condition, and may cause more side effects. Do not start or stop any medicine without doctor or pharmacist approval.

OVERDOSE

If overdose is suspected, contact your local poison control center or emergency room immediately. US residents can call the US national poison hotline at 1-800-222-1222. Canadian residents should call their local poison control center directly.

MISSED DOSE

If you miss a dose, use it as soon as you remember. If it is within 2 hours of the next dose, skip the missed dose and resume your usual dosing schedule. It is important not to miss doses of this drug.

STORAGE

Store at room temperature at 77 degrees F (25 degrees C) away from light and moisture. Brief storage between 59-86 degrees F (15-30 degrees C) is permitted. Do not store in bathroom. Keep the desiccant in the bottle and do not swallow it. Keep all medicines away from children and pets.

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.

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