







## **DRUG INTERACTIONS**

This drug should not be used with the following medications because very serious interactions may occur: ribavirin, zalcitabine. If you are currently using any of these medications, tell your doctor or pharmacist before starting this drug. Tell your doctor of all prescription and nonprescription medication you may use, especially of: drugs that can cause liver problems (e.g., isoniazid), drugs that affect the bone marrow (e.g., anticancer drugs, chloramphenicol), tenofovir, trimethoprim/ sulfamethoxazole, atovaquone, fluconazole, methadone, valproic acid, ganciclovir, interferon-alpha, probenecid, protease inhibitors (e.g., indinavir, ritonavir, nelfinavir). This medication contains abacavir, zidovudine, and lamivudine. Do not take other medicine containing abacavir, zidovudine, or lamivudine unless directed to do so by your doctor. This product can interfere with certain lab tests (e.g., liver). Inform laboratory personnel that you are using this medication. Do not start or stop any medicine without doctor or pharmacist approval.

#### USES

Abacavir sulfate/lamivudine/zidovudine, alone or in combination with other drugs, is used to treat human immunodeficiency virus (HIV) infection. It works by slowing the growth of the virus. This medication is not intended for use in children. This medication is not a cure for HIV infection. You may continue to have illnesses associated with HIV infection. This medication does not reduce the risk of passing the virus to others through sexual contact or blood contamination. One group of HIV medications (the nucleoside/nucleotide reverse transcriptase inhibitors-NRTIs such as zidovudine and lamivudine) are very useful. However, NRTIs are recommended to be used in combination with other groups of HIV medications in order to be effective. Consult your doctor or pharmacist for more details.

#### **HOW TO USE**

Take this medication by mouth, usually twice daily with or without food; or take as directed by your doctor. It is important to continue taking this medication and other anti-HIV medications exactly as prescribed by your doctor. Do not stop taking this medication or skip any doses unless directed to do so by your doctor. Read the Medication Guide provided by your pharmacist. Carry the "Warning Card" with you at all times.

## SIDE EFFECTS

Trouble sleeping or dizziness may occur. If any of these effects persist or worsen, contact your doctor or pharmacist promptly. Tell your doctor immediately if any of these serious side effects occur: loss of appetite, muscle weakness, mental or mood changes. Tell your doctor immediately if any of these highly unlikely but serious side effects occur: seizures, dark urine, yellowing eyes or skin, rapid breathing, change in the amount of urine, unusual bleeding or bruising. Changes in body fat may occur while you are taking this medication (e.g., 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 therapy with your doctor, as well as the possible role of exercise to reduce this side effect. An allergic reaction to this drug is unlikely, but stop taking this drug and seek immediate medical attention if it occurs. Symptoms of an allergic reaction include: fever, nausea, vomiting, diarrhea, skin rash, extreme tiredness, headache, tingling or numbness of the hands or feet, muscle weakness, achiness, cough, sore throat, mouth sores, stomach pain, itching, swelling, severe dizziness, trouble breathing. If you notice other effects not listed above, contact your doctor or pharmacist.

## OVERDOSE

Lif 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. Symptoms of overdose may include nausea, drowsiness, or mental/mood changes.

## MISSED DOSE

If you miss a dose, contact your doctor or pharmacist immediately (see Precautions section for more details).

## STORAGE

Store at room temperature between 59 and 86 degrees F (15 to 30 degrees C) away from light and moisture.

## **PRECAUTIONS**

Tell your doctor your medical history, especially of: liver or kidney disease, heart disease, alcohol dependence, blood disorders, bone marrow problems, hepatitis B infection, diabetes, major injury/surgery/infection, allergies (especially to abacavir, zidovudine, lamivudine). This drug may make you dizzy; use caution engaging in activities requiring alertness such as driving or using machinery. Avoid alcoholic beverages. If you must stop using this drug due to an allergic reaction, never use this drug or abacavir again; death could result. Consult your doctor and read the "Warning Card" for more information. If you stop using this drug (e.g., forget to order a refill) even for a short time and restart the drug, you have an increased chance of developing the very serious (possibly fatal) allergic reaction. Do not stop treatment unless specifically instructed to do so. Know the symptoms of this allergic reaction (see side effects section). Consult your doctor or pharmacist before restarting this medication, and be sure you have easy access to medical care if you are restarting treatment. This medication should not be used in teenagers or adults who weigh less than 88 pounds (40 kg). Consult your doctor for more information. Caution is advised when using this medication in the elderly, as they may be more sensitive to drug effects. This medication should be used only when clearly needed during pregnancy. Discuss the risks and benefits with your doctor. The zidovudine in this medication passes into breast milk. Because breast milk can transmit HIV, do not breast-feed.

## **WARNING**

This medication contains abacavir. Infrequently, abacavir has been associated with severe (sometimes fatal) allergic (hypersensitivity) reactions. See Side Effects section for the symptoms of this allergic reaction. If you think you are having an allergic reaction to this medication, stop using this medication and seek medical attention immediately. This medication should not be restarted following an allergic reaction because more severe symptoms may occur, including death. Severe allergic reactions, including death, have occurred in patients who restart this medication, even if they have had no history or unrecognized symptoms of an allergic reaction. Do not stop and then restart this medication unless directed to do so by your doctor. If you do stop and restart this medication, make sure you have easy access to medical care. This medication contains zidovudine, which has been associated with blood cell problems (e.g., neutropenia, anemia), especially in patients with advanced HIV disease. Prolonged use of zidovudine has been associated with muscle weakness (myopathy). Tell your doctor immediately if you have unusual weakness or tiredness or persistent sore throat or fever. Lactic acid build-up in the blood (lactic acidosis) and severe liver problems (hepatomegaly with steatosis) have been reported with the use of abacavir, zidovudine, and lamivudine, alone and in combination with other HIV medications. Tell your doctor immediately if you have symptoms of lactic acid build-up and liver problems, which include unusual tiredness, rapid breathing, dark urine, or yellowing eyes and skin. The long-term effects of this medication are unknown at this time. Information on the use of this medication in patients with advanced HIV (viral load levels greater than 100,000 copies/ml) is limited at this time.

**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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Revised November 2010