MEDICATION GUIDE
Abacavir Tablets, USP
(ah-BAH-kah-veer)

What is the most important information I should know about abacavir tablets?
Abacavir can cause serious side effects, including:
- Serious allergic reaction (hypersensitivity reaction) that can cause death have happened with abacavir tablets and other abacavir-containing products. Your risk of this allergic reaction is much higher if you have a gene variation called HLA-B*5701. Your healthcare provider can determine with a blood test if you have this gene variation.
- Nausea, vomiting, diarrhea, abdominal (stomach area) pain.
- Generally ill feeling, extreme tiredness, or achiness.
- Shortness of breath, cough, sore throat.

A list of these symptoms is on the Warning Card your pharmacist gives you. Carry this Warning Card with you at all times.

If you stop abacavir tablets because of an allergic reaction, never take abacavir or any other abacavir-containing medicine (EPZICOM®, TRUVIÇÃO®, and TRIZIVIR®) again.

- If you take abacavir tablets or any other abacavir-containing medicine again after you have had an allergic reaction, within hours you may get life-threatening symptoms that may include very low blood pressure or death.
- If you stop abacavir tablets for any other reason, even for a few days, and you are not allergic to abacavir, talk with your healthcare provider before taking it again. Taking abacavir tablets again can cause a serious allergic or life-threatening reaction, even if you never had an allergic reaction to it before.

If your healthcare provider tells you that you can take abacavir tablets again, start taking it when you are around medical help or people who can call a healthcare provider if you need one.

- Build-up of acid in your blood (lactic acidosis). Lactic acidosis can happen in some people who take abacavir tablets. Lactic acidosis is a serious medical emergency that can cause death. Call your healthcare provider right away if you get any of the following symptoms that could be signs of lactic acidosis:
  - feel very weak or tired
  - unusual (not normal) muscle pain
  - trouble breathing
  - stomach pain with nausea and vomiting
  - feel cold, especially in your arms and legs
  - feel dizzy or light-headed
  - have a fast or irregular heartbeat

- Serious liver problems can happen in people who take abacavir. In some cases, these serious liver problems can lead to death. Your liver may become large (hepatomegaly) and you may develop fat in your liver (steatosis) when you take abacavir tablets. Call your healthcare provider right away if you have any of the following signs of liver problems:
  - your skin or the white part of your eyes turns yellow (jaundice)
  - dark or “tea-colored” urine
  - light-colored stools (bowel movements)

You may be more likely to get lactic acidosis or serious liver problems if you are female, very overweight (obese), or have been taking nucleoside analogue medicines for a long time.

What is abacavir tablets?
Abacavir tablet is a prescription HIV-1 (Human Immunodeficiency Virus type 1) medicine used with other antiretroviral medicines to treat HIV-1 infection. HIV-1 is the virus that causes Acquired Immune Deficiency Syndrome (AIDS).

The safety and effectiveness of abacavir has not been established in children under 3 months of age.

When used with other antiretrovirals to treat HIV-1 infection, abacavir tablet may help:
- reduce the amount of HIV-1 in your blood. This is called “viral load”.
- increase the number of CD4+ (T) cells in your blood, that help fight off other infections.

Reducing the amount of HIV-1 and increasing the CD4+ (T) cells in your blood may help improve your immune system. This may reduce your risk of death or getting infections that can happen when your immune system is weak (opportunistic infections).

Abacavir tablets does not cure HIV-1 infection or AIDS. You must keep taking HIV-1 medicines to control HIV-1 infection and decrease HIV-related illnesses.

Avoid doing things that can spread HIV-1 infection to others.
- Do not share or re-use needles or other injection equipment.
- Do not share personal items that can have blood or body fluids on them, like toothbrushes and razor blades.
- Do not have any kind of sex without protection. Always practice safer sex by using a latex or polyurethane condom to lower the chance of sexual contact with any body fluids such as semen, vaginal secretions, or blood.

Ask your healthcare provider if you have any questions about how to prevent passing HIV to other people.

Who should not take abacavir tablets?
Do not take abacavir tablets if you:
- have a certain type of gene variation called the HLA-B*5701 allele. Your healthcare provider will test you for this before prescribing treatment with abacavir.
- are allergic to abacavir or any of the ingredients in abacavir tablets. See the end of this Medication Guide for a complete list of ingredients in abacavir tablets.
- have liver problems.

What should I tell my healthcare provider before taking abacavir tablets?
Before you take abacavir tablets, tell your healthcare provider if you:
- have been tested and know whether or not you have a particular gene variation called HLA-B*5701.
- have or have had liver problems, including hepatitis B or C virus infection.
- have heart problems, smoke, or have diseases that increase your risk of heart disease such as high blood pressure, high cholesterol, or diabetes.
- drink alcohol or take medicines that contain alcohol.
- are pregnant or plan to become pregnant. Taking abacavir tablets during pregnancy has not been associated with an increased risk of birth defects. Talk to your healthcare provider if you are pregnant or plan to become pregnant.

Pregnancy Registry. There is a pregnancy registry for women who take antiretroviral medicines during pregnancy. The purpose of this registry is to collect information about the health of you and your baby. Talk to your healthcare provider about how you can take part in this registry.
- are breastfeeding or plan to breastfeed. Do not breastfeed if you take abacavir tablets.
  - You should not breastfeed if you have HIV-1 because of the risk of passing HIV-1 to your baby.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Some medicines interact with abacavir. Keep a list of your medicines to show your healthcare provider and pharmacist. You can ask your healthcare provider or pharmacist for a list of medicines that interact with abacavir. Do not start taking a new medicine without telling your healthcare provider. Your healthcare provider can tell you if it is safe to take abacavir with other medicines.
You should not take abacavir tablets if you also take:

- abacavir (EPZICOM, TRIUMEQ, or TRIZIVIR)

Tell your healthcare provider if you take:

- any other medicine to treat HIV-1
- methadone

How should I take abacavir tablet?

- Take abacavir tablet exactly as your healthcare provider tells you.
- Do not change your dose or stop taking abacavir tablets without talking with your healthcare provider. If you miss a dose of abacavir tablets, take it as soon as you remember. Do not take 2 doses at the same time. If you are not sure about your dosing, call your healthcare provider.
- Stay under the care of a healthcare provider while taking abacavir tablets.
- Abacavir tablet may be taken with or without food.
- For children aged 3 months and older, your healthcare provider will prescribe a dose of abacavir based on your child’s body weight.
- Tell your healthcare provider if you or your child has trouble swallowing tablets. Abacavir comes as a tablet or as a liquid (oral solution).
- Do not run out of abacavir tablets. The virus in your blood may increase and the virus may become harder to treat. When your supply starts to run out, get more from your healthcare provider or pharmacy.
- If you take too much abacavir, call your healthcare provider or go to the nearest hospital emergency room right away.

What are the possible side effects of abacavir tablets?

- Abacavir can cause serious side effects including:
- See “What is the most important information I should know about abacavir tablets?”

Changes in your immune system (Immune Reconstitution Syndrome) can happen when your start taking HIV-1 medicines. Your immune system may get stronger and begin to fight infections that have been hidden in your body for a long time. Tell your healthcare provider right away if you start having new symptoms after you start taking abacavir tablets.

Changes in body fat can happen in people who take HIV-1 medicines. These changes may include an increased amount of fat in the upper back and neck (“buffalo hump”), breast, and around the middle of your body (trunk). Loss of fat from the legs, arms, and face may also happen. The exact cause and long-term health effects of these conditions are not known.

Heart attack (myocardial infarction). Some HIV-1 medicines including abacavir tablet may increase your risk of heart attack.

The most common side effects of abacavir tablets in adults include:

- nausea
- headache
- generally not feeling well
- tiredness
- vomiting
- bad dreams or sleep problems

The most common side effects of abacavir tablets in children include:

- fever and chills
- nausea
- vomiting
- rash
- ear, nose, or throat infections

Tell your healthcare provider if you have any side effect that bothers you or that does not go away.

These are not all the possible side effects of abacavir tablets. For more information, ask your healthcare provider or pharmacist. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store abacavir tablets?

- Store below 30°C.

Keep abacavir tablets and all medicines out of the reach of children.

General information for safe and effective use of abacavir tablets

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use abacavir tablets for a condition for which it was not prescribed. Do not give abacavir tablets to other people, even if they have the same symptoms that you have. It may harm them.

If you would like more information, talk with your healthcare provider, You can ask your healthcare provider or pharmacist for the information about abacavir that is written for healthcare professionals.

What are the ingredients in abacavir tablets?

Tablets

Active ingredient: Abacavir sulfate, USP

Inactive ingredients: microcrystalline cellulose, sodium starch glycolate, colloidal silicon dioxide, magnesium stearate. The tablets are coated with opadry yellow which contains hypromellose, titanium dioxide, triacetin, iron oxide yellow, and polysorbate 80.

Manufactured by:

[Image]

HETERO™

HETERO LABS LIMITED

22-110, I.D.A., Jeevanbheeman, Hyderabad-500055, India.

Revised: November, 2015

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This Medication Guide has been approved by the U.S. Food and Drug Administration.
WARNING CARD
Abacavir Tablets USP

Patients taking abacavir tablets may have a serious allergic reaction (hypersensitivity reaction) that can cause death. If you get a symptom from 2 or more of the following groups while taking abacavir tablets, call your healthcare provider right away to find out if you should stop taking this medicine.

<table>
<thead>
<tr>
<th>Symptom(s)</th>
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<tbody>
<tr>
<td>Group 1  Fever</td>
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<tr>
<td>Group 2  Rash</td>
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<tr>
<td>Group 3  Nausea, vomiting, diarrhea, or abdominal (stomach area) pain</td>
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<tr>
<td>Group 4  Generally ill feeling, extreme tiredness, or achiness</td>
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<tr>
<td>Group 5  Shortness of breath, cough, or sore throat</td>
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</tbody>
</table>

Always carry this Warning Card with you to help recognize symptoms of this allergic reaction.

WARNING CARD
Abacavir Tablets USP

If you must stop treatment with abacavir tablets because you have had an allergic reaction to abacavir, NEVER take abacavir tablets or another abacavir-containing medicine (EPZICOM®, TRIUMEQ® or TRIZIVIR®) again. If you take abacavir tablets or another abacavir-containing medicine again after you have had an allergic reaction, WITHIN HOURS you may get life-threatening symptoms that may include very low blood pressure or death. Please read the Medication Guide for additional information on abacavir tablets.

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November 2015

Manufactured by:

HETERO LABS LIMITED, 22-110, I.D.A., Jeedimetla, Hyderabad-500 055, India.

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Size: 120x54 mm
Pharma Code: 3274
SPEC: 300GSM PGB BOARD FRONT AND BACK SIDE PRINTING, NO. OF COLOURS: 1 (BLACK)