

MEDICATION GUIDE

**Abacavir tablets USP 300 mg**

(A bak’ a vir)

**What is the most important information I should know about abacavir tablets?**

**Abacavir tablets 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.

**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 Abacavir tablets.**

	Symptom(s)
Group 1	Fever
Group 2	Rash
Group 3	Nausea, vomiting, diarrhea, abdominal (stomach area) pain
Group 4	Generally ill feeling, extreme tiredness, or achiness
Group 5	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 tablets or any other abacavir-containing medicine (EPZICOM®, TRIUMEQ®, or TRIZIVIR®) again.**

- If you have an allergic reaction, dispose of any unused abacavir. Ask your pharmacist how to properly dispose of medicines.
- 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 tablets, 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.**

**What is abacavir tablet?**

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 tablets has not been established in children under 3 months of age.

**When used with other antiretroviral medicines to treat HIV-1 infection, abacavir tablets 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 do not cure HIV-1 infection or AIDS.** You must keep taking HIV-1 medicines to control HIV-1 infection and decrease HIV-related illnesses.

**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 tablets.
- 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. 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 tablets. **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 tablets. **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 tablets with other medicines.

**Tell your healthcare provider if you take:**

- any other medicine to treat HIV-1
- methadone
- riociguat

**How should I take abacavir tablets?**

- **Take abacavir tablets 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 tablets may be taken with or without food.
- For children aged 3 months and older, your healthcare provider will prescribe a dose of abacavir tablets based on your child’s body weight.
- Tell your healthcare provider if you or your child has trouble swallowing tablets. Abacavir tablets 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 tablets, call your healthcare provider or go to the nearest hospital emergency room right away.

**What are the possible side effects of abacavir tablets?**

• **Abacavir tablets can cause serious side effects including:**

• **See “What is the most important information I should know about abacavir tablets?”**

• **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
- feel cold, especially in your arms and legs
- unusual (not normal) muscle pain
- feel dizzy or light-headed
- trouble breathing
- have a fast or irregular heartbeat
- stomach pain with nausea and vomiting

• **Serious liver problems** can happen in people who take abacavir tablets. 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)
- loss of appetite for several days or longer
- nausea
- pain, aching, or tenderness on the right side of your stomach area

**You may be more likely to get lactic acidosis or serious liver problems if you are female or very overweight (obese).**

• **Changes in 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.

• **Heart attack (myocardial infarction).** Some HIV-1 medicines including abacavir tablets 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 abacavir tablets at room temperature, between 68°F to 77°F (20°C to 25°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 Guides. 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 tablets that is written for healthcare professionals.

For more information call Strides Pharma Inc. at 1-877-244-9825 or go to [www.strides.com](http://www.strides.com) or FDA at 1-800-FDA-1088 or [www.fda.gov/medwatch](http://www.fda.gov/medwatch).

**What are the ingredients in abacavir tablets?**

Active ingredient: abacavir sulfate

Inactive ingredients:

colloidal silicon dioxide, magnesium stearate, micro-crystalline cellulose and sodium starch glycolate. The tablets are coated with Opadry Yellow that is made of Hypromellose, Macrogol/PEG, yellow iron oxide and titanium dioxide.

This Medication Guide has been approved by the US Food and Drug Administration.

COMBIVIR®, EPIVIR®, EPZICOM®, TRIUMEQ®, TRIZIVIR®, ZIAGEN® and ADEMPAS® are registered trademarks of their respective owners and are not trademarks of Strides Pharma Science Ltd. The makers of these brands are not affiliated with and do not endorse Strides Pharma Science Ltd. or its products

Manufactured by:

**Strides Pharma Science Ltd.**  
Bengaluru - 562106, India

Distributed by:

**Strides Pharma Inc.**  
East Brunswick, NJ 08816, USA

**Revised: 05/2022**

**Medication Guide available at:**  
**[www.strides.com/medication-guides](http://www.strides.com/medication-guides)**