MEDICATION GUIDE
Abacavir, Dolutegravir and LamivudineTablets
(a-BAK-a-vir, doe loo teg' ra vir, la miv' ue deen)

What is the most important information I should know about abacavir, dolutegravir and lamivudine tablets?
Abacavir, dolutegravir and lamivudine tablets can cause serious side effects, including:

- **Serious allergic reactions (hypersensitivity reaction)** that can cause death have happened with abacavir, dolutegravir and lamivudine tablets and other abacavir-containing products. Your risk of this allergic reaction to abacavir 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, dolutegravir and lamivudine tablets, call your healthcare provider right away to find out if you should stop taking abacavir, dolutegravir and lamivudine 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, dolutegravir and lamivudine tablets because of an allergic reaction, never take abacavir, dolutegravir and lamivudine tablets (abacavir, dolutegravir and lamivudine), or any other medicine that contains abacavir or dolutegravir (DOVATO, EPZICOM, JULUCA,TIVICAY,TIVICAY PD,TRIZIVIR, or ZIAGEN) again.

- o If you have an allergic reaction, dispose of any unused abacavir, dolutegravir and lamivudine tablets. Ask your pharmacist how to properly dispose of medicines.
- o If you take abacavir, dolutegravir and lamivudine 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.
- o If you stop abacavir, dolutegravir and lamivudine tablets for any other reason, even for a few days, and you are not allergic to abacavir, dolutegravir and lamivudine tablets, talk with your healthcare provider before taking it again. Taking abacavir, dolutegravir and lamivudine 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, dolutegravir and lamivudine tablets again, start taking it when you are around medical help or people who can call a healthcare provider if you need one.

- **Worsening of Hepatitis B virus (HBV) infection.** Your healthcare provider will test you for HBV infection before you start treatment with abacavir, dolutegravir and lamivudine tablets. If you have HBV infection and take abacavir, dolutegravir and lamivudine tablets, your HBV may get worse (flare-up) if you stop taking abacavir, dolutegravir and lamivudine tablets. A "flare-up" is when your HBV infection suddenly returns in a worse way than before.
- o Do not run out of abacavir, dolutegravir and lamivudine tablets. Refill your prescription or talk to your healthcare provider before your abacavir, dolutegravir and lamivudine tablets are all gone.
- o Do not stop abacavir, dolutegravir and lamivudine tablets without first talking to your healthcare provider.
- o If you stop taking abacavir, dolutegravir and lamivudine tablets, your healthcare provider will need to check your health often and do blood tests regularly for several months to check your liver function and monitor your HBV infection. It may be necessary to give you a medicine to treat hepatitis B. Tell your healthcare provider about any new or unusual symptoms you may have after you stop taking abacavir, dolutegravir and lamivudine tablets.
- **Resistant HBV.** If you have human immunodeficiency virus-1 (HIV-1) and HBV, the HBV can change (mutate) during your treatment with abacavir, dolutegravir and lamivudine tablets and become harder to treat (resistant). Your healthcare provider may give you other medicines to treat HBV infection if you have HIV-1 and HBV infections and take abacavir, dolutegravir and lamivudine tablets.
- **For more information about side effects, see "What are the possible side effects of abacavir, dolutegravir and lamivudine tablets?"**

What are abacavir, dolutegravir and lamivudine tablets?

Abacavir, dolutegravir and lamivudine tablets are prescription medicines used to treat HIV-1 infection in adults and children who are at least 3 months of age and weigh at least 13.2 pounds (6 kg).

HIV-1 is the virus that causes Acquired Immune Deficiency Syndrome (AIDS).

Abacavir, dolutegravir and lamivudine tablets contain the prescription medicines abacavir, dolutegravir, and lamivudine.

- Abacavir, dolutegravir and lamivudine tablets should not be used by itself in people who have resistance to certain types of medicines.

Do not take abacavir, dolutegravir and lamivudine 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, dolutegravir and lamivudine tablets.
- are allergic to abacavir, dolutegravir, lamivudine, or any of the ingredients in abacavir, dolutegravir and lamivudine tablets. See the end of this Medication Guide for a complete list of ingredients in abacavir, dolutegravir and lamivudine tablets.
- take dofetilide. Taking abacavir, dolutegravir and lamivudine tablets and dofetilide can cause side effects that may be serious or life-threatening.
- have certain liver problems.

Before you take abacavir, dolutegravir and lamivudine tablets, tell your healthcare provider about all of your medical conditions, including 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 kidney problems.
- 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 about the benefits and risks of treatment with abacavir, dolutegravir and lamivudine tablets during pregnancy.

Pregnancy Registry. There is a pregnancy registry for those who take abacavir, dolutegravir and lamivudine tablets during pregnancy. The purpose of this registry is to collect information about the health of you and your baby. Talk with your healthcare provider about how you can take part in this registry.

- are breastfeeding or plan to breastfeed. Abacavir, dolutegravir and lamivudine tablets passes to your baby in your breast milk. Talk with your healthcare provider about the following risks to your baby from breastfeeding during treatment with abacavir, dolutegravir and lamivudine tablets:
- o the HIV-1 virus may pass to your baby if your baby does not have HIV-1 infection.
- o the HIV-1 virus may become harder to treat if your baby has HIV-1 infection.
- o your baby may get side effects from abacavir, dolutegravir and lamivudine tablets.

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, dolutegravir and lamivudine tablets. Keep a list of your medicines to show your healthcare provider and pharmacist when you get a new medicine.

- You can ask your healthcare provider or pharmacist for a list of medicines that interact with abacavir, dolutegravir and lamivudine 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, dolutegravir and lamivudine tablets with other medicines.

How should I take abacavir, dolutegravir and lamivudine tablets?

- **Take abacavir, dolutegravir and lamivudine tablets exactly as your healthcare provider tells you to take it.**
- Do not change your dose, switch medicines or stop taking abacavir, dolutegravir and lamivudine tablets without talking with your healthcare provider first.
- **Abacavir, dolutegravir and lamivudine tablets are not the same asTRIUMEQ PD tablets for oral suspension and cannot be substituted for each other. Check to make sure you receive the correct dosage form each time you or your child's prescription is filled to avoid using the wrong medicine.**
- Your child's healthcare provider will prescribe abacavir, dolutegravir and lamivudine tablets based on your child's weight.
- Do **not** chew, cut, or crush abacavir, dolutegravir and lamivudine tablets.
- Abacavir, dolutegravir and lamivudine tablets may be taken with or without food.
- If you take antacids, laxatives, or other medicines that contain aluminum, magnesium, or buffered medicines, abacavir, dolutegravir and lamivudine tablets should be taken at least 2 hours before or 6 hours after you take these medicines.
- If you need to take iron or calcium supplements, or multivitamin supplements that contain iron or calcium, by mouth during treatment with abacavir, dolutegravir and lamivudine tablets:
- o If you take abacavir, dolutegravir and lamivudine tablets with food, you may take these supplements at the same time that you take abacavir, dolutegravir and lamivudine tablets.
- o If you do not take abacavir, dolutegravir and lamivudine tablets with food, take abacavir, dolutegravir and lamivudine tablets at least 2 hours before or 6 hours after you take these supplements.
- If you miss a dose of abacavir, dolutegravir and lamivudine tablets, take it as soon as you remember. Do not take 2 doses at the same time or take more than your healthcare provider tells you to take.
- Stay under the care of a healthcare provider during treatment with abacavir, dolutegravir and lamivudine tablets.
- Do not run out of abacavir, dolutegravir and lamivudine tablets. The virus in your blood may increase and the virus may become harder to treat. When your supply starts to run low, get more from your healthcare provider or pharmacy.
- If you take too much abacavir, dolutegravir and lamivudine, call your healthcare provider or go to the nearest hospital emergency room right away.

What are the possible side effects of abacavir, dolutegravir and lamivudine tablets?
Abacavir, dolutegravir and lamivudine tablets can cause serious side effects, including:

- **See "What is the most important information I should know about abacavir, dolutegravir and lamivudine tablets ?"**
- **Liver problems.** People with a history of hepatitis B or C virus may have an increased risk of developing new or worsening changes in certain liver function tests during treatment with abacavir, dolutegravir and lamivudine tablets. Liver problems including liver failure have also happened with abacavir, dolutegravir and lamivudine tablets in people without a history of liver disease or other risk factors. Liver failure resulting in liver transplant has also been reported with abacavir, dolutegravir and lamivudine tablets. Your healthcare provider may do blood tests to check your liver. **Call your healthcare provider right away if you develop any of the signs or symptoms of liver problems listed below.**
  - o your skin or the white part of your eyes turns yellow (jaundice)
  - o loss of appetite
  - o dark or "tea-colored" urine
  - o nausea or vomiting
  - o light colored stools (bowel movements)
  - o pain, aching, or tenderness on the right side of your stomach area
- **Too much lactic acid in your blood (lactic acidosis).** Too much lactic acid is a serious medical emergency that can lead to death. **Call your healthcare provider right away if you get any of the following symptoms that could be signs of lactic acidosis:**
  - o feel very weak or tired
  - o feel cold, especially in your arms and legs
  - o unusual (not normal) muscle pain
  - o feel dizzy or lightheaded
  - o trouble breathing
  - o have a fast or irregular heartbeat
  - o stomach pain with nausea and vomiting
- **Lactic acidosis can also lead to severe liver problems,** which can lead to death. Your liver may become large (hepatomegaly), and you may develop fat in your liver (steatosis). **Call your healthcare provider right away if you get any of the signs or symptoms of liver problems which are listed above under "Liver problems."**
- **You may be more likely to get lactic acidosis or severe liver problems if you are female or very overweight (obese).**
- **Changes in your immune system (Immune Reconstitution Syndrome)** can happen when you 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, dolutegravir and lamivudine tablets.
- **Heart attack.** Some HIV-1 medicines including abacavir, dolutegravir and lamivudine tablets may increase your risk of heart attack.
- **The most common side effects of abacavir, dolutegravir and lamivudine tablets include:**
  - o trouble sleeping
  - o headache
  - o tiredness

These are not all the possible side effects of abacavir, dolutegravir and lamivudine tablets.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1800FDA1088.

How should I store abacavir, dolutegravir and lamivudine tablets?

- Store abacavir, dolutegravir and lamivudine tablets at Store below 30°C in the original bottle. Keep the bottle tightly closed and protect it from moisture.
- The bottle of abacavir, dolutegravir and lamivudine tablets contains a desiccant packet to help keep your medicine dry (protect it from moisture). Do not remove the desiccant packet from the bottle.
- Abacavir, dolutegravir and lamivudine tablets come in a child-resistant package.

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

General information about the safe and effective use of abacavir, dolutegravir and lamivudine tablets.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use abacavir, dolutegravir and lamivudine tablets for a condition for which it was not prescribed. Do not give abacavir, dolutegravir and lamivudine tablets to other people, even if they have the same symptoms that you have. It may harm them. You can ask your pharmacist or healthcare provider for information about abacavir, dolutegravir and lamivudine tablets that is written for health professionals.

What are the ingredients in abacavir, dolutegravir and lamivudine tablets?

Active ingredients: abacavir, dolutegravir, and lamivudine

Inactive ingredients:

Abacavir, dolutegravir and lamivudine tablets: magnesium stearate, mannitol, microcrystalline cellulose, povidone and sodium starch glycolate.

Tablet filmcoating contains: black iron oxide, iron oxide red, iron oxide yellow, polyethylene glycol, polyvinyl alcohol, talc and titanium dioxide.

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For more information call Hetero Labs Limited at 1-866-495-1995.

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

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Initiator	**Reviewer**	**Marketing**	**RA**	**RP**
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