MEDICATION GUIDE
TRIUMEQ® (TRI-u-meck)
(abacavir, dolutegravir, and lamivudine)
tablets

What is the most important information I should know about TRIUMEQ?
TRIUMEQ can cause serious side effects, including:

- **Serious allergic reactions (hypersensitivity reaction)** that can cause death have happened with TRIUMEQ 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 TRIUMEQ, call your healthcare provider right away to find out if you should stop taking TRIUMEQ.

	Symptom
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 TRIUMEQ because of an allergic reaction, never take TRIUMEQ (abacavir, dolutegravir and lamivudine) or any other abacavir− or dolutegravir− containing medicines (EPZICOM ®, TIVICAY®, TRIZIVIR ® , or ZIAGEN ®) again.

  - If you take TRIUMEQ 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 TRIUMEQ for any other reason, even for a few days, and you are not allergic to TRIUMEQ, talk with your healthcare provider before taking it again. Taking TRIUMEQ 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 TRIUMEQ 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 TRIUMEQ. 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 TRIUMEQ. 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). **Call your healthcare provider right away if you get any of the following signs or symptoms 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, very overweight (obese), or have been taking nucleoside analogue medicines for a long time.

- **Worsening of hepatitis B virus in people who have HIV-1 infection.** If you have Human Immunodeficiency Virus type 1 (HIV-1) and hepatitis B virus (HBV) infection, your HBV may get worse (flare-up) if you stop taking TRIUMEQ. A "flare-up" is when your HBV infection suddenly returns in a worse way than before. Worsening liver disease can be serious and may lead to death.
    - Do not run out of TRIUMEQ. Refill your prescription or talk to your healthcare provider before your TRIUMEQ is all gone.
    - Do not stop TRIUMEQ without first talking to your healthcare provider.
    - If you stop taking TRIUMEQ, your healthcare provider will need to check your health often and do blood tests regularly for several months to check your liver.
- **Resistant Hepatitis B Virus (HBV).** If you have HIV-1 and hepatitis B, the hepatitis B virus can change (mutate) during your treatment with TRIUMEQ and become harder to treat (resistant).
- **Use with interferon and ribavirin− based regimens.** Worsening of liver disease that has caused death has happened in people infected with both HIV-1 and hepatitis C virus who were taking antiretroviral medicines, and were also being treated for hepatitis C with interferon with or without ribavirin. If you are taking TRIUMEQ and interferon with or without ribavirin, tell your healthcare provider if you have any new symptoms.

What is TRIUMEQ?

TRIUMEQ is a prescription HIV−1 (Human Immunodeficiency Virus type 1) medicine used alone or with other antiretroviral medicines to treat HIV-1 infection. HIV-1 is the virus that causes Acquired Immune Deficiency Syndrome (AIDS). TRIUMEQ contains 3 prescription medicines, abacavir (ZIAGEN), dolutegravir (TIVICAY) and lamivudine (EPIVIR®).

- TRIUMEQ is not for use by itself in people who have or have had resistance to abacavir, dolutegravir, or lamivudine.

TRIUMEQ should not be used in children.

When used alone or with other antiretroviral medicines to treat HIV-1 infection, TRIUMEQ 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, which 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).

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

What should I tell my healthcare provider before taking TRIUMEQ?
Before you take TRIUMEQ, 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 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. It is not known if TRIUMEQ will harm your unborn baby. 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 TRIUMEQ.**

    - 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 TRIUMEQ. **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 TRIUMEQ. **Do not start taking a new medicine without telling your healthcare provider.** Your healthcare provider can tell you if it is safe to take TRIUMEQ with other medicines.
You should not take TRIUMEQ if you also take:

- abacavir (EPZICOM, TRIZIVIR, or ZIAGEN)
- lamivudine (COMBIVIR ®, DUTREBIS™, EPIVIR ®, EPIVIR-HBV ®, EPZICOM, or TRIZIVIR)
- emtricitabine (ATRIPLA ®, COMPLERA ®, EMTRIVA ®,STRIBILD ®, or TRUVADA ®)

Tell your healthcare provider if you take:

- antacids, laxatives, or other medicines that contain aluminum, magnesium, sucralfate (CARAFATE ®), or buffered medicines. TRIUMEQ should be taken at least 2 hours before or 6 hours after you take these medicines.
- anti-seizure medicines:
    - oxcarbazepine (TRILEPTAL ®)
    - phenytoin (DILANTIN ®, DILANTIN ®-125, PHENYTEK ®)
    - phenobarbital
    - carbamazepine (CARBATROL ®, EQUETRO ®, TEGRETOL ®, TEGRETOL ®-XR, TERIL ®, EPITOL ®)
- any other medicine to treat HIV-1
- iron or calcium supplements taken by mouth. Supplements containing calcium or iron may be taken at the same time with TRIUMEQ if taken with food. Otherwise, TRIUMEQ should be taken at least 2 hours before or 6 hours after you take these medicines.
- medicines used to treat hepatitis virus infections, such as interferon or ribavirin
- a medicine that contains metformin
- methadone
- rifampin (RIFATER ®, RIFAMATE ®, RIMACTANE ®, RIFADIN ®)
- St. John's wort (*Hypericum perforatum*)

How should I take TRIUMEQ?

- **Take TRIUMEQ exactly as your healthcare provider tells you.**
- Do not change your dose or stop taking TRIUMEQ without talking with your healthcare provider. If you miss a dose of TRIUMEQ, 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 TRIUMEQ.
- TRIUMEQ may be taken with or without food.
- Do not run out of TRIUMEQ. 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 TRIUMEQ, call your healthcare provider or go to the nearest hospital emergency room right away.

What are the possible side effects of TRIUMEQ?

- **TRIUMEQ can cause serious side effects including:**
- **See "What is the most important information I should know about TRIUMEQ?"**
- **Changes in liver tests.** People with a history of hepatitis B or C virus may have an increased risk of developing new or worsening changes in certain liver tests during treatment with TRIUMEQ. Your healthcare provider may do tests to check your liver function before and during treatment with TRIUMEQ.
- **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 TRIUMEQ.
- **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 TRIUMEQ may increase your risk of heart attack.

The most common side effects of TRIUMEQ include:

- trouble sleeping
- headache
- tiredness

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 TRIUMEQ. 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 TRIUMEQ?

- Store TRIUMEQ at room temperature between 68°F to 77°F (20°C to 25°C).
- Store TRIUMEQ in the original bottle.
- Keep the bottle of TRIUMEQ tightly closed and protected from moisture.
- The bottle of TRIUMEQ contains a desiccant packet to help keep your medicine dry (protect it from moisture). Keep the desiccant packet in the bottle. Do not remove the desiccant packet.

Keep TRIUMEQ and all medicines out of the reach of children.

General information about the safe and effective use of TRIUMEQ
Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use TRIUMEQ for a condition for which it was not prescribed. Do not give TRIUMEQ 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 information about TRIUMEQ that is written for health professionals.
For more information go to www.TRIUMEQ.comor call 1-877-844-8872.

What are the ingredients in TRIUMEQ?
Active ingredients: abacavir, dolutegravir, and lamivudine
Inactive ingredients: D-mannitol, magnesium stearate, microcrystalline cellulose, povidone, and sodium starch glycolate.
Tablet film−coating contains: iron oxide black, iron oxide red, macrogol/PEG, polyvinyl alcohol–part hydrolyzed, talc, and titanium oxide.

Manufactured for:	by:
ViiV Healthcare	GlaxoSmithKline
Research Triangle Park, NC 27709	Research Triangle Park, NC 27709

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