Abacavir, Dolutegravir, and Lamivudine

Brand Names: US
Triumeq

Brand Names: Canada
Triumeq

Warning

- Unsafe and sometimes deadly allergic effects with organ failure may happen with this drug. Tell your doctor about any fever, rash, feeling tired, upset stomach, throwing up, loose stools, belly pain, flu-like signs, sore throat, cough, or trouble breathing. Do not restart this drug if you have had an allergic reaction.

- The chance of allergic effects is raised in people who have a certain gene called HLA-B*5701. Do not take this drug if you have the HLA-B*5701 gene. Your doctor will check you for this gene before you start this drug. Talk with your doctor.

- Read the warning card and carry it with you at all times. It tells the signs to watch for in case an allergy happens.

- Hepatitis B has gotten worse when this drug was stopped in some people with hepatitis B. Close follow-up for a few months is needed when therapy is stopped in people who have hepatitis B. Do not stop taking this drug without calling your doctor. Talk with your doctor.

What is this drug used for?

- It is used to treat HIV infection.
What do I need to tell my doctor BEFORE I take this drug?

For all patients taking this drug:

- If you have an allergy to this drug or any part of this drug.

- If you are allergic to any drugs like this one, any other drugs, foods, or other substances. Tell your doctor about the allergy and what signs you had, like rash; hives; itching; shortness of breath; wheezing; cough; swelling of face, lips, tongue, or throat; or any other signs.

- If you have been tested and know that you have a gene type called HLA-B*5701.

- If you have any of these health problems: Kidney disease or liver disease.

- If you are taking any of these drugs: Dofetilide, etravirine, nevirapine, oxcarbazepine, phenobarbital, phenytoin, or St. John’s wort.

- If you are taking a drug that has sorbitol in it.

- If you are pregnant or may be pregnant. Do not take this drug if you are in the first trimester of pregnancy.

- If you are breast-feeding. Do not breast-feed while you take this drug.

Children:

- If your child weighs less than 88 pounds (40 kilograms). This drug is not for use in children who weigh less than 88 pounds (40 kilograms).

This is not a list of all drugs or health problems that interact with this drug.

Tell your doctor and pharmacist about all of your drugs (prescription or OTC, natural products, vitamins) and health problems. You must check to make sure that it is safe for you to take this drug with all of your drugs and health problems. Do not start, stop, or change the dose of any drug without checking with your doctor.

What are some things I need to know or do while I take this drug?

- Tell all of your health care providers that you take this drug. This includes
your doctors, nurses, pharmacists, and dentists.

- Have blood work checked as you have been told by the doctor. Talk with the doctor.

- A higher chance of heart attack was seen in people who took abacavir. It is not known if abacavir caused this effect. Talk with the doctor.

- Use care if you have risks for heart disease (high blood pressure, high cholesterol, overweight, high blood sugar or diabetes, cigarette smoking, man older than 40 years of age, other family members with early heart disease, woman after change of life). Talk with your doctor.

- If this drug is stopped because you have an allergy to it, do not restart it. It may not be safe to restart this drug. Throw away any of this drug that you have not taken. If you are not sure how to throw away unused drugs, check with your pharmacist.

- If this drug is stopped for any other reason, do not restart it without talking to the doctor. It could be very risky to restart on your own.

- Talk with your doctor before you drink alcohol.

- Some other drugs may need to be taken at some other time than this drug. If you take other drugs, check with your doctor or pharmacist to see if you need to take them at some other time than this drug.

- This drug is not a cure for HIV. Stay under the care of your doctor.

- This drug does not stop the spread of diseases like HIV or hepatitis that are passed through blood or having sex. Do not have any kind of sex without using a latex or polyurethane condom. Do not share needles or other things like toothbrushes or razors. Talk with your doctor.

- This drug may rarely cause swollen liver and an acid health problem in the blood. This may be deadly in some cases. The chance may be higher in women, in overweight people, and in people who have taken drugs like this one for a long time. Talk with your doctor.

- Liver problems have happened with this drug. Sometimes, this has been very bad and a liver transplant has been needed. Talk with the doctor.

- If you have had hepatitis B or C, talk with your doctor.

- If you have hepatitis C and HIV, talk with your doctor. Liver function has
gotten worse in people who were taking this drug and interferon alfa with or without ribavirin. Sometimes, this has been deadly.

- A pancreas problem (pancreatitis) has happened in children taking lamivudine with or without other HIV drugs. Sometimes this has been deadly. If you have questions, talk with the doctor.

- This drug may cause harm to the unborn baby if you take it while you are pregnant.

- If you are able to get pregnant, a pregnancy test will be done to show that you are NOT pregnant before starting this drug. Talk with your doctor.

- Use birth control that you can trust to prevent pregnancy while taking this drug.

- If you are pregnant or you get pregnant while taking this drug, call your doctor right away.

What are some side effects that I need to call my doctor about right away?

**WARNING/CAUTION:** Even though it may be rare, some people may have very bad and sometimes deadly side effects when taking a drug. Tell your doctor or get medical help right away if you have any of the following signs or symptoms that may be related to a very bad side effect:

- Signs of an allergic reaction, like rash; hives; itching; red, swollen, blistered, or peeling skin with or without fever; wheezing; tightness in the chest or throat; trouble breathing, swallowing, or talking; unusual hoarseness; or swelling of the mouth, face, lips, tongue, or throat.

- Signs of liver problems like dark urine, feeling tired, not hungry, upset stomach or stomach pain, light-colored stools, throwing up, or yellow skin or eyes.

- Signs of too much lactic acid in the blood (lactic acidosis) like fast breathing, fast heartbeat, a heartbeat that does not feel normal, very bad upset stomach or throwing up, feeling very sleepy, shortness of breath, feeling very tired or weak, very bad dizziness, feeling cold, or muscle pain or cramps.

- Signs of kidney problems like unable to pass urine, change in how much urine is passed, blood in the urine, or a big weight gain.
- Signs of a pancreas problem (pancreatitis) like very bad stomach pain, very bad back pain, or very bad upset stomach or throwing up.
- Very bad dizziness or passing out.
- Chest pain or pressure.
- Mouth sores.
- Eye irritation.
- Muscle pain or weakness.
- Joint pain.
- A burning, numbness, or tingling feeling that is not normal.
- Swelling.
- Shortness of breath.
- Swollen gland.

- Changes in your immune system can happen when you start taking drugs to treat HIV. If you have an infection that you did not know you had, it may show up when you take this drug. Tell your doctor right away if you have any new signs after you start this drug, even after taking it for several months. This includes signs of infection like fever, sore throat, weakness, cough, or shortness of breath.

**What are some other side effects of this drug?**

All drugs may cause side effects. However, many people have no side effects or only have minor side effects. Call your doctor or get medical help if any of these side effects or any other side effects bother you or do not go away:

- Headache.
- Not able to sleep.
- Feeling tired or weak.

These are not all of the side effects that may occur. If you have questions about side effects, call your doctor. Call your doctor for medical advice about side effects.

You may report side effects to your national health agency.
How is this drug best taken?

Use this drug as ordered by your doctor. Read all information given to you. Follow all instructions closely.

- Take with or without food.
- Keep taking this drug as you have been told by your doctor or other health care provider, even if you feel well.
- It is important that you do not miss or skip a dose of this drug during treatment.
- Do not run out of this drug.
- If you take products that have iron, aluminum, calcium, or magnesium in them (like some antacids or vitamins), you may need to take them at some other time than this drug. Talk with your doctor or pharmacist.
- Many other drugs interact with this drug. Talk with your doctor and pharmacist to make sure that it is safe for you to use this drug with all of your other drugs.

What do I do if I miss a dose?

- Take a missed dose as soon as you think about it.
- If it is close to the time for your next dose, skip the missed dose and go back to your normal time.
- Do not take 2 doses at the same time or extra doses.
- If you are not sure what to do if you miss a dose, call your doctor.

How do I store and/or throw out this drug?

- Store at room temperature.
- Store in a dry place. Do not store in a bathroom.
- Store in the original container. Do not take out the antimoisture cube or packet.
- Keep lid tightly closed.
- Keep all drugs in a safe place. Keep all drugs out of the reach of children and...
• Throw away unused or expired drugs. Do not flush down a toilet or pour down a drain unless you are told to do so. Check with your pharmacist if you have questions about the best way to throw out drugs. There may be drug take-back programs in your area.

General drug facts

• If your symptoms or health problems do not get better or if they become worse, call your doctor.

• Do not share your drugs with others and do not take anyone else’s drugs.

• Keep a list of all your drugs (prescription, natural products, vitamins, OTC) with you. Give this list to your doctor.

• Talk with the doctor before starting any new drug, including prescription or OTC, natural products, or vitamins.

• Some drugs may have another patient information leaflet. If you have any questions about this drug, please talk with your doctor, nurse, pharmacist, or other health care provider.

• If you think there has been an overdose, call your poison control center or get medical care right away. Be ready to tell or show what was taken, how much, and when it happened.

Consumer Information Use and Disclaimer

This information should not be used to decide whether or not to take this medicine or any other medicine. Only the healthcare provider has the knowledge and training to decide which medicines are right for a specific patient. This information does not endorse any medicine as safe, effective, or approved for treating any patient or health condition. This is only a brief summary of general information about this medicine. It does NOT include all information about the possible uses, directions, warnings, precautions, interactions, adverse effects, or risks that may apply to this medicine. This information is not specific medical advice and does not replace information you receive from the healthcare provider. You must talk with the healthcare provider for complete information about the risks and benefits of using this medicine.
If you have any questions or concerns, talk with a member of your healthcare team. You can reach them Monday through Friday from 9:00 AM to 5:00 PM at _________________. After 5:00 PM, during the weekend, and on holidays, please call______________________. If there’s no number listed, or you’re not sure, call 212-639-2000.