

# abacavir (Ziagen)

#### WHAT IS ABACAVIR?

Abacavir, also known as abacavir sulfate or ABC (brand name Ziagen), is a drug used as part of <u>antiretroviral therapy (ART)</u>. The FDA approved abacavir in 1998 as an <u>antiretroviral drug (ARV)</u> for people with HIV infection. Generic versions have been approved under <u>PEPFAR</u>. Abacavir is manufactured by <u>ViiV Healthcare</u>.

Abacavir is a type of drug called a <u>nucleoside reverse transcriptase inhibitor (NRTI)</u>. NRTIs bind to and block reverse transcriptase (an HIV enzyme). HIV uses reverse transcriptase to convert its RNA into DNA (reverse transcription). Blocking reverse transcriptase and reverse transcription prevents HIV from replicating.

When used in combination with other ARVs to treat HIV infection, abacavir may help:

- Reduce the amount of HIV in your blood. This is called <u>viral load</u>.
- Increase the number of <u>CD4 cells</u> in your blood that help fight off other infections.

Reducing the amount of HIV and increasing CD4 cells in your blood may help improve your immune system. This may reduce your risk of death or getting <u>opportunistic infections (OIs)</u> that can happen when your immune system is weak. <u>Read more about viral suppression.</u>

Abacavir <u>does not cure</u> HIV infection or AIDS. You must keep taking HIV medicines to control HIV infection and decrease HIV-related illnesses.

#### WHO SHOULD TAKE ABACAVIR?

Abacavir is a prescription HIV medicine used in combination with other ARVS to treat HIV infection in adults and children 3 months old and older. The safety and effectiveness of abacavir has not been established in children under 3 months of age. Abacavir has not been carefully studied in the elderly (65 years of age and older).

All people living with HIV should be on ART to keep healthy AND not transmit the virus to others. You and your healthcare provider should consider your CD4 cell count, your viral load, any symptoms you are having, and your preferences when deciding which HIV medications are right for you. Read more about U.S. ART guidelines.

## WHO SHOULD NOT TAKE ABACAVIR?

Do not take abacavir if you:

- Have a gene variation called the HLA-B\*5701 allele. Your healthcare provider will test you for this before prescribing treatment with abacavir (see below).
- Are allergic to abacavir or any of the ingredients in this drug.
- Have moderate or severe liver disease.

## WHAT SHOULD I TELL MY HEALTHCARE PROVIDER BEFORE TAKING ABACAVIR?

Before you take abacavir, tell your healthcare provider about all of your medical conditions, and in particular if you:

- Have been tested and know whether or not you have a particular gene variation called HLA-B\*5701 (see below).
- Have or have had liver problems, including <u>hepatitis B virus (HBV)</u> or <u>hepatitis C virus</u> (HCV) infection.
- Have heart problems, smoke, or have diseases that increase your risk of <u>cardiovascular disease</u> (CVD) such as high blood pressure, high cholesterol, or <u>diabetes</u>.
- Drink alcohol or take medicines that contain alcohol.

Talk to your healthcare provider if you are pregnant or plan to become pregnant during treatment with abacavir. There is a pregnancy registry for people who take ARVs during pregnancy. The purpose of this registry is to collect information about the health of you and your baby and monitor outcomes in people exposed to ARVs during pregnancy. Talk to your healthcare provider about how you can take part in this registry. Read more about pregnancy and HIV.

Talk to your healthcare provider if you are breastfeeding or plan to breastfeed during treatment with abacavir. Do not breastfeed if you take abacavir. You should not breastfeed if you have HIV because of the risk of passing HIV to your baby.

#### WHAT ABOUT DRUG RESISTANCE?

Mutations are copies of the virus that are different from the original virus. Some mutations can keep multiplying even when you are taking an ARV. When this happens, the drug will stop working. This is called developing resistance to the drug. Sometimes, if your virus develops resistance to one ARV, it will also have resistance to other ARVs. This is called cross-resistance. Read more about HIV drug resistance.

Resistance can develop quickly. It is very important to take ARVs according to instructions, on schedule, and not to skip or reduce doses.

## **HOW IS ABACAVIR TAKEN?**

Abacavir is taken by mouth as a tablet or oral solution. The recommended dosage of abacavir for adults is 600 mg daily taken orally as either 300 mg twice daily or 600 mg once daily, in combination with other ARVs. The recommended dosage of abacavir for children varies based on the child's weight and age. Your healthcare provider will determine the correct dosage.

Abacavir can be taken with or without food.

**You need to take abacavir in combination with other ARVs.** Your healthcare provider will tell you what medicines to take and how to take them.

Abacavir is also available in several <u>combination medications</u>. Combination HIV medicines contain 2 or more HIV medicines from 1 or more drug classes.

- abacavir/dolutegravir/lamivudine (<u>Triumeq</u>)
- abacavir/lamivudine (Epzicom)

## WHAT ARE THE SIDE EFFECTS?

When you start any ARV, you may have temporary <u>side effects</u> such as headaches, nausea, indigestion, or a general sense of feeling ill. These side effects usually get better or disappear over time.

The most common side effects of abacavir in adults are nausea, headaches, generally not feeling well, <u>fatigue</u>, vomiting, and bad dreams or sleep problems. The most common side effects of abacavir in children include fever and chills, rash, nausea, ear, nose, or throat infections, and vomiting.

Abacavir can cause serious side effects including:

**Serious allergic reactions (hypersensitivity reaction).** Serious allergic reactions (hypersensitivity reactions) that can cause death have happened with abacavir 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 this test comes back positive, you should add abacavir to the list of medications you are allergic to.

If you get a symptom from 2 or more of the following groups while taking abacavir, call your healthcare provider right away to find out if you should stop taking abacavir:

Group 1 Fever Group 2 Rash

Group 3 Nausea, vomiting, diarrhea, abdominal 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 because of an allergic reaction, never take abacavir or any other abacavir-containing medicine (Epzicom, Triumeq, 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 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 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 again can cause a serious allergic or life-threatening reaction, even if you never had an allergic reaction to it before.

**Too much lactic acid in your blood (lactic acidosis).** <u>Lactic acidosis</u> is a serious but rare medical emergency that can cause death. Tell your healthcare provider right away if you develop any of these symptoms:

- 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

**Severe liver problems.** In rare cases, severe liver problems can happen that can lead to death. Your liver may become large (hepatomegaly) and you may develop fat in your liver (steatosis). Tell your healthcare provider right away if you get these symptoms:

- 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
- Pain, aching, or tenderness on the right side of your stomach area
- Nausea or vomiting

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

**Immune Reconstitution Inflammatory Syndrome (IRIS).** IRIS is a side effect that can happen when you start taking HIV medications. Your immune system might get stronger and begin to fight infections that have been hidden in your body for a long time. This may result in an inflammatory response which may require further evaluation and treatment. Tell your healthcare provider right away if you experience any new symptoms after starting abacavir.

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

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

#### **HOW DOES ABACAVIR REACT WITH OTHER DRUGS?**

All ARVs can <u>interact</u> with other drugs or supplements you are taking. These interactions can change the amount of each drug or substance in your bloodstream and cause an under- or overdose. New interactions are constantly being identified. **Tell your healthcare provider about all the medicines you take**, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Your healthcare provider can tell you if it is safe to take abacavir with other medicines.

Research studies have identified drug interactions between abacavir and the following drugs: methadone and

<u>riociguat (Adempas)</u>. For some people taking abacavir, an increased methadone dose may be required. For some people taking abacavir, the riociguat dose may need to be reduced.

## **MORE INFORMATION**

Download the full <u>Prescribing Information</u>

Download the Medication Guide

Download the **Consumer Medicine Information** leaflet

Check out the ViiV Healthcare Patient Assistance Program

Get a <u>ViiV Healthcare Savings Card</u>

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