

# Abacavir (Ziagen)

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## What is Ziagen?

- Ziagen is an anti-HIV medication. It is in a category of HIV medications called nucleoside reverse transcriptase inhibitors (NRTIs). Ziagen prevents HIV from altering the genetic material of healthy T-cells. This prevents the cells from producing new virus and decreases the amount of virus in the body.
- Ziagen, manufactured by GlaxoSmithKline, was approved for the treatment of HIV by the U.S. Food and Drug Administration (FDA) in 1998.
- Ziagen is available in pharmacies as a single drug, which is always combined with at least two other anti-HIV drugs, or in combination tablets: Trizivir® and Epzicom™. Each Trizivir tablet contains a single dose of Ziagen, Retrovir® (AZT), and Epivir® (3TC). Each Epzicom tablet contains a single dose of Ziagen and Epivir.

## What is known about Ziagen?

- Ziagen can be taken once a day or twice a day. Once-a-day dosing requires taking two 300mg tablets every 24 hours. Twice-a-day dosing requires taking one 300mg

tablet every 12 hours. Trizivir® tablets, which contain Ziagen, Retrovir® (AZT), and Epivir® (3TC), are taken twice a day: one tablet in the morning and one tablet in the evening. Epzicom™ tablets, containing Ziagen and Epivir, are taken once a day.

- For children, a liquid formula of Ziagen is available. The correct dose depends on the child's body weight and will change as the child gets older.
- Ziagen can be taken with or without food.
- Numerous studies have demonstrated that Ziagen is effective for the treatment of HIV when combined with other anti-HIV drugs. Ziagen should not be taken alone (as monotherapy) or with just one other anti-HIV drug.
- The United States Department of Health and Human Services (DHHS) lists Ziagen as an "alternative" NRTI for HIV-positive people starting anti-HIV treatment for the first time (Retrovir® [AZT], Epivir® [3TC], and Viread® [tenofovir] are listed as "preferred" NRTI options). If Ziagen is used, the DHHS recommends combining it with either Epivir or Emtriva® (FTC) plus a protease inhibitor or an NNRTI.

- Therapy with Ziagen can cause certain changes (mutations) in HIV's structure to occur. Some mutations will prevent Ziagen from working against HIV. Some of these mutations can also prevent Retrovir® (AZT) and/or Efavirenz® (EFV) from working against HIV. Similarly, Ziagen might not work well against HIV strains already resistant to Retrovir and/or Efavirenz. If your viral load does not go undetectable or becomes detectable (and increases) while you are taking an anti-HIV drug regimen that contains Ziagen, your doctor can order a drug-resistance test to determine if your HIV has mutations that are causing resistance to Ziagen and to help you figure out which NRTIs your HIV is still sensitive to.

#### What about drug interactions?

- Ziagen can increase the amount of the protease inhibitor Agenerase® (amprenavir), and probably Lexiva® (fosamprenavir) in the body. However, it is not necessary to change the doses of either Ziagen or Agenerase/Lexiva.
- Ziagen can increase the rate at which methadone, a drug often used to help manage symptoms of heroin withdrawal, is cleared from the body. If you are taking methadone and Ziagen at the same time, it might be necessary to increase your methadone dose.

#### What about side effects?

- Approximately 8% of people who take Ziagen are allergic to it and can experience a "hypersensitivity reaction." This can be serious and may require that Ziagen therapy be stopped. A hypersensitivity reaction usually appears during the second week of therapy, but it can take as long as six weeks to notice any symptoms. The most common symptoms are fever

and rash, followed by headaches, stomach upset, feeling tired, sore throat, cough, and shortness of breath. These symptoms usually get worse over time and it is important that you report them to your doctor immediately.

- If your doctor tells you that you are allergic or are having a hypersensitivity reaction, you will be told to stop the drug. If you stop taking Ziagen because of these symptoms, you must not start the drug again, or start any drug that contains Ziagen (e.g. Trizivir® or Epzicom™). Some people who were allergic to the drug and restarted therapy saw their symptoms return immediately and became very ill.
- Lactic acidosis, which can be fatal, and severe liver problems have been reported in people taking NRTIs including Ziagen. Contact your doctor immediately if you experience nausea, vomiting, or unusual or unexpected stomach discomfort; weakness and tiredness; shortness of breath; weakness in the arms and legs; yellowing of the skin or eyes; or pain in the upper stomach area.
- Some of the more common side effects include appetite loss, headaches, feeling crummy (malaise), nausea, vomiting, and diarrhea. Very often, these side effects improve within a few months/weeks of starting Ziagen.
- Anti-HIV drug regimens containing NRTIs, including Ziagen, can cause increased fat levels (cholesterol and triglycerides) in the blood, abnormal body-shape changes (lipodystrophy; including increased fat around the abdomen, breasts, and back of the neck, as well as decreased fat in the face, arms, and legs), and diabetes.

## Who should not take Ziagen?

- Before taking this medication, tell your doctor if you have kidney disease or liver disease.
- You may not be able to take Ziagen, or you may require lower doses or special monitoring during treatment, if you have any of these conditions.
- Be sure to tell your doctor if you have allergies to medications, including Ziagen. If you've ever taken Ziagen in the past and stopped the drug for any reason, be sure to tell your doctor. If you have ever taken Ziagen, or any drug that contains Ziagen (e.g. Trizivir® or Epzicom™), in the past and had a hypersensitivity reaction, you must not take Ziagen again.
- Ziagen is classified by the FDA as a pregnancy category C drug. All the FDA-approved anti-HIV drugs are classified as either category B or C. Pregnancy category B means that animal studies have failed to demonstrate a risk to the fetus, but there are no adequate and well-controlled studies in pregnant women. Pregnancy category C means that animal studies have shown an adverse effect on the fetus and there are no adequate and well-controlled studies in humans, but potential benefits may

warrant use of the drug in pregnant women despite potential risks. HIV-positive women who become pregnant should discuss the benefits and possible side effects of anti-HIV treatment to help protect their babies from HIV.

- It is not known whether Ziagen passes into breast milk and what effects it may have on a nursing baby. However, to prevent HIV transmission of the virus to uninfected babies, it is recommended that HIV-positive mothers not breast-feed.

## Where can I learn more about clinical trials that are using Ziagen?

- If you would like to find out if you are eligible for any clinical trials that include Ziagen, there is an interactive web site run by amfAR, the American Foundation for AIDS Research.
- Another useful service for finding clinical trials is *AIDSinfo.nih.gov*, a site run by the U.S. National Institutes of Health. They have "health information specialists" you can talk to at their toll-free number at 1-800-HIV-0440 (1-800-448-0440).

## a note about this publication

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