ABCD1890LX-ABVP220
CORE SALES AID - DDAVAC Submission
12/5/98

NEW
POWER
AGAINST
HIV.

abacavir sulfate 300 mg

new

VIAZEN
ONE TABLET BID

20-24

ZDV in combination with other antiretroviral agents is indicated for the treatment of HIV-1 infection. This indication is based on analyses of surrogate markers in controlled studies of up to 24 weeks in duration. At present, there are no results from controlled trials evaluating long-term suppression of HIV-RNA or disease progression with ZDV.

20-24
New power against HIV

- A unique NRTI that delivers significant reduction in viral load
- One tablet BID, with or without food, encourages adherence
- Easily incorporated into multidrug regimens
- ZIAGEN plus Combivir® (lamivudine 150 mg/zidovudine 300 mg) Tablets can achieve undetectable viral load in most therapy-naive patients and may preserve future treatment options

ZIAGEN is available as 300-mg tablets and 20-mg/mL oral solution

Product shot of tablet bottle, suspension bottle, and tablets


©1996 Glaxo Welcome Inc. All rights reserved. ABC01890 December 1996
new for HIV

I AM HERE

Indicated for the treatment of HIV-1 infection in combination with other antiretroviral agents, based on analyses of surrogate markers in controlled studies of up to 24 weeks. There are no results from controlled trials evaluating long-term suppression of HIV-RNA or disease progression with ZIAGEN.

GlaxoWellcome
INTRODUCING THE FIRST GUANOSINE ANALOGUE: NRTIs

I AM NEW POWER AGAINST HIV.
I am new

Ziagen
abacavir sulfate 300 mg tablets

I am unique.
Ziagen is the first guanosine nucleoside analogue for the treatment of HIV infection in combination therapy (based on surrogate markers).

I drive down viral load
75% of therapy-naïve patients receiving Ziagen with lamivudine, zidovudine achieved viral loads <400 c/mL at 16 weeks, compared with 39% receiving lamivudine, zidovudine alone (Table 1). Ziagen can be effective in therapy-experienced patients, but the effects may be less.

I am two pills a day, with or without food.
The easy dosing of Ziagen—one 300-mg tablet BID with or without food—encourages adherence.

I am easily incorporated into multidrug regimens.
Ziagen is not significantly metabolized by the cytochrome P450 enzyme system.

I help protect future treatment options.
Ziagen plus Combivir (lamivudine 150 mg/zidovudine 300 mg) tablets can achieve viral load <400 copies/mL in most therapy-naïve patients and may preserve future treatment options.

Note: Hypersensitivity reactions have been reported with Ziagen, including rash, fever, angioedema, and anaphylaxis (Table 1). Ziagen should not be restarted following a hypersensitivity reaction. The most common adverse events were nausea, vomiting, headache, and fatigue, and most cases resolved within 2 weeks. More serious reactions may include fever, rash, and anaphylaxis. Monitor patients closely. Construction and death.

52-54
168 Figure 1
389-390
113-114
134-135
168 Figure 1
211-213
329-332 Table 1

Glaxo Wellcome
If you have HIV...

I AM NEW POWER AGAINST HIV.

ZIAGEN is a powerful new medicine for HIV combination therapy. Easy to take: just one tablet, twice a day, with or without food.

Please see important safety information in the right.
Most people who took ZIAGEN as part of their first combination therapy achieved undetectable viral load at 16 weeks—without taking a protease inhibitor. Of all patients taking ZIAGEN with lamivudine + zidovudine in this clinical trial, 75 out of 100 had viral load undetectable below 400 copies/mL.

**MEDICATION GUIDE**

**What is the most important Information I should know about Ziagen?**

About 3% of patients (3 in 100) who take Ziagen have a hypersensitivity reaction (a serious allergic reaction). If you have two or more of the following sets of symptoms, you may be having this kind of reaction:

- fever
- nausea, vomiting, diarrhea, or abdominal pain
- severe tiredness, run-down feeling, achingness, or generally ill feeling
- skin rash (redness and/or itching)

A written list of these symptoms is on the Warning Card provided by your pharmacist. You should carry this Warning Card with you. **IF YOU NOTICE THESE SYMPTOMS WHILE TAKING ZIAGEN, STOP TAKING ZIAGEN AND CALL YOUR DOCTOR IMMEDIATELY.**

If you must stop treatment with Ziagen because you have had this serious reaction, **NEVER** take Ziagen again. If you take Ziagen again after you have had this serious reaction, **WITHIN HOURS** you may experience a life-threatening lowering of your blood pressure or death.

You should return all of your unused Ziagen to your doctor or pharmacist for proper disposal.

Ziagen can have other serious side effects. Be sure to read "What are the possible side effects of Ziagen?" in the section below.
What is Ziajen?
Ziajen is an oral medication used to treat HIV infection. Ziajen is taken orally as a tablet, or a strawberry-banana flavored oral solution. It belongs to a class of anti-HIV medicines called nucleoside analogue reverse transcriptase inhibitors (NRTIs). Ziajen is only proven to work when taken in combination with other anti-HIV medications. When used in combination with these other medications, Ziajen helps lower the amount of HIV found in your blood and keep your immune system as healthy as possible so that it can help fight infection. However, Ziajen does not have these effects in all patients. Ziajen does not cure HIV infection or AIDS. At this time, there is no evidence that Ziajen will help you live longer or have fewer of the medical problems that are associated with HIV infection or AIDS. Because of this, you must be sure to be seen regularly by your health care provider.

Who should not take Ziajen?
Do not take Ziajen if you have ever had a hypersensitivity reaction (a serious allergic reaction) to Ziajen.

How should I take Ziajen?
Take Ziajen exactly as your doctor prescribes it.

The usual dosage for adults (at least 16 years of age) is one 300-mg tablet twice a day.

Adolescents and children from 3 months to 16 years of age can also take Ziajen. Your doctor will tell you if the oral solution or tablet is best for your child. Also, your child’s doctor will decide the right dose based on your child’s weight and age. Ziajen has not been studied in children under 3 months of age.

Ziajen can be taken with food or on an empty stomach.

To help make sure that your anti-HIV therapy is as effective as it can be, be very careful to take all of your medication exactly as your doctor prescribed it and do not skip any doses.

If you miss a dose of Ziajen, take the missed dose immediately. Then, take the next dose at the regularly scheduled time.

When your supply of Ziajen and other anti-HIV drugs starts to run low, get more from your doctor or pharmacy. It is very important that you take anti-HIV drugs as prescribed by your doctor because the amount of virus in your blood may increase if one or more of the drugs is stopped, even for a short time.

What should I avoid while taking Ziajen?
Ziajen has not been shown to reduce the risk of passing HIV to others through sexual contact or blood contamination. Continue to practice safe sex while taking Ziajen. Do not use or share dirty needles.

Talk to your doctor if you are pregnant or if you become pregnant while taking Ziajen. Ziajen has not been studied in pregnant women and the risk to the unborn child is not known.

Mothers with HIV should not breastfeed their infants because HIV in the breast milk can be passed to the infant.

Tell your doctor if you have kidney or liver problems.

What are the possible or reasonably likely side effects of Ziajen?
Some people have had a hypersensitivity reaction (a serious allergic reaction) to Ziajen, which can be fatal. Instruct your doctor what to do if such a reaction is suspected. The most important information I should know about Ziajen?

The class of medicines to which Ziajen belongs (NRTIs) can cause a condition called lactic acidosis, together with an enlarged liver. In some cases, this condition can be fatal. Women are more likely than men to experience this rare but serious side effect.

Ziajen can cause other side effects. In studies, the most common side effects with Ziajen were nausea, vomiting, diarrhea, fatigue, headache, and loss of appetite. Most of these side effects did not cause people to stop taking Ziajen. This listing of side effects is not complete. Your doctor or pharmacist can discuss with you a more complete list of side effects with Ziajen. Tell your doctor promptly about any side effects you have.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Ask a health care professional about any concerns about Ziajen. Professional labeling is available to your doctor and other health care professionals.

Date of Issue: [Insert Date]

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

www.siajen.com

Glaxo Wellcome
HIV
A division of Glaxo Wellcome Inc.
Research Triangle Park, NC 27709
Web: http://www.gw.com
Ziagen
abacavir sulfate 300 mg tablets

Full Prescribing Information

ZIAGEN in combination with other antiretroviral agents is indicated for the treatment of HIV-1 infection. This indication is based on analyses of surrogate markers in controlled studies of up to 24 weeks in duration. At present, there are no results from controlled trials evaluating long-term suppression of HIV-RNA or disease progression with ZIAGEN.