

INTRODUCING

NEW
POWER
AGAINST
HIV.

new
ZiagenTM
abacavir sulfate ³⁰⁰mg
ONE TABLET BID

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.

20-24



Ziagen™

abacavir sulfate 300 mg tablets

New power against HIV

PI Lines

- 52-56
 - 168-170
 - 388-389
 - 113-114
 - 134-135
 - 168-170
- 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

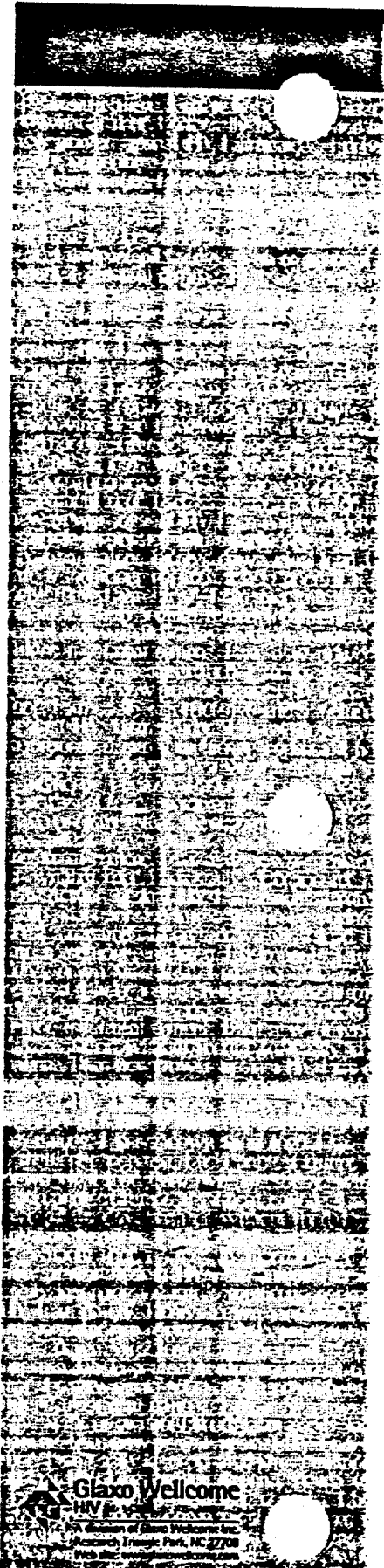
Product shot of tablet bottle, suspension bottle, and tablets

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

References: 1. Faletto MB, Miller WH, Garvey EP, St Clair MH, Daluge SM. Unique intracellular activation of the potent anti-human immunodeficiency virus agent 1592U89. *Antimicrob Agents Chemother*. 1997;41:1099-1107. 2. Data on file, Glaxo Wellcome Inc.

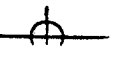
Please see accompanying full Prescribing Information.

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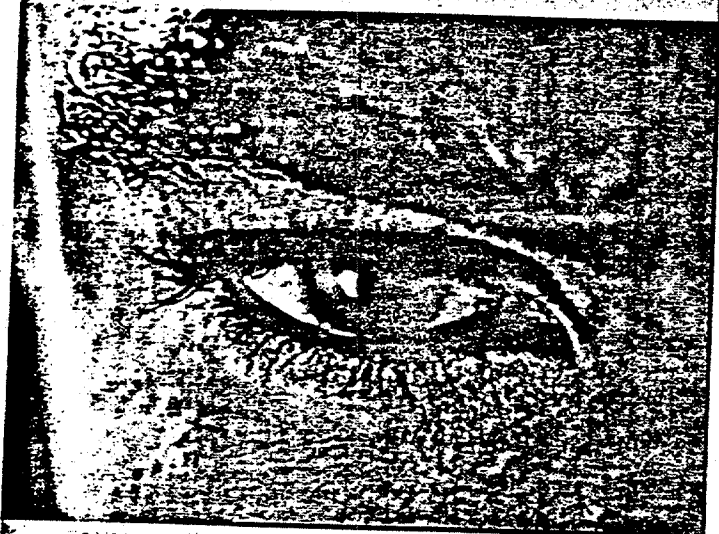


Glaxo Wellcome
HIV
Research Triangle Park, NC 27709

drive down viral load. I am two pills a day, with or



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.

20-24

GlaxoWellcome

INTRODUCING THE FIRST GUANOSINE ANALOGUE NRTI

I AM
NEW
POWER
AGAINST
HIV.

199-200
318-319
316-318

I am new

Ziagen™

abacavir sulfate 300 mg tablets

I am unique

ZIAGEN is the first guanosine nucleoside analogue for the treatment of HIV-1 infection in combination therapy (based on surrogate markers).

52-54

I drive down viral load

75% of therapy-naïve patients receiving ZIAGEN with lamivudine + zidovudine achieved viral load < 400 copies/mL at 16 weeks, compared with 35% receiving lamivudine + zidovudine alone (intent-to-treat analysis). ZIAGEN can be effective in therapy-experienced patients, but the effects may be less.

168
Figure 1

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.

389-390

I am easily incorporated into multidrug regimens

ZIAGEN is not significantly metabolized by the cytochrome P450 enzyme system.

113-114
134-135

I help protect future treatment options

ZIAGEN + 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.

168
Figure 1

Fatal hypersensitivity reactions have been associated with therapy with ZIAGEN. ZIAGEN should be discontinued as soon as a hypersensitivity reaction is suspected. ZIAGEN should not be restarted following a hypersensitivity reaction because more severe symptoms will recur within hours and may include life-threatening hypotension and death. Lactic acidosis and severe hepatomegaly with steatosis, including fatal cases, have been reported with the use of all NRTIs including ZIAGEN. The most common adverse events were nausea, headache, malaise and fatigue, and nausea and vomiting.

211-213
329-332
Table 1

Lamivudine and zidovudine are now available in one tablet, COMBIVIR®. See the Amptec HIV-1 MONITOR® Test. Please see brief summary of complete Prescribing Information for ZIAGEN on adjacent page.

Glaxo Wellcome
HIV-1
A Division of Glaxo Wellcome Inc.
Research Triangle Park, NC 27709
Web site: www.ziagen.com

For call 1-888-XXX-XXXX

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, achiness, 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 Ziagen?

Ziagen is an oral medication used to treat HIV infection. Ziagen 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). Ziagen is only proven to work when taken in combination with other anti-HIV medications. When used in combination with these other medications, Ziagen 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, Ziagen does not have these effects in all patients.

Ziagen does not cure HIV infection or AIDS. At this time, there is no evidence that Ziagen 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 Ziagen?

Do not take Ziagen if you have ever had a hypersensitivity reaction (a serious allergic reaction) to Ziagen.

How should I take Ziagen?

Take Ziagen 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 Ziagen. 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. Ziagen has not been studied in children under 3 months of age.

Ziagen 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 Ziagen, take the missed dose immediately. Then, take the next dose at the regularly scheduled time.

When your supply of Ziagen 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 Ziagen?

Ziagen 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 using Ziagen. Do not use or share dirty needles.

Talk to your doctor if you are pregnant or if you become pregnant while taking Ziagen. Ziagen 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 Ziagen?

Some people have had a hypersensitivity reaction (a serious allergic reaction) to Ziagen, which can be fatal. Instructions on how to recognize a possible reaction, as well as what to do if such a reaction is suspected, are discussed in the section "What is the most important information I should know about Ziagen?"

The class of medicines to which Ziagen 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.

Ziagen can cause other side effects. In studies, the most common side effects with Ziagen were nausea, vomiting, malaise or fatigue, headache, diarrhea, and loss of appetite. Most of these side effects did not cause people to stop taking Ziagen. This listing of side effects is not complete. Your doctor or pharmacist can discuss with you a more complete list of side effects with Ziagen. Talk to 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 Ziagen. Professional labeling is available to your doctor and other health care professionals.

Date of Issue: _____ PL no. _____

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

www.ZIAGEN.com



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HIV

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Research Triangle Park, NC 27709
Web site: www.glaxowellcome.com



Y P A R E H E R A L I M N O T A N I B M O L I R O F I E R



ABC
PID
12/7

ZiagenTM
abacavir sulfate 300 mg tablets

Full Prescribing Information

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