

CENTER FOR DRUG EVALUATION AND RESEARCH

Application Number 20-977

20-978

FINAL PRINTED LABELING

Ziagen™

abacavir sulfate 300 mg tablets

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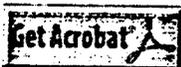
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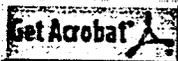
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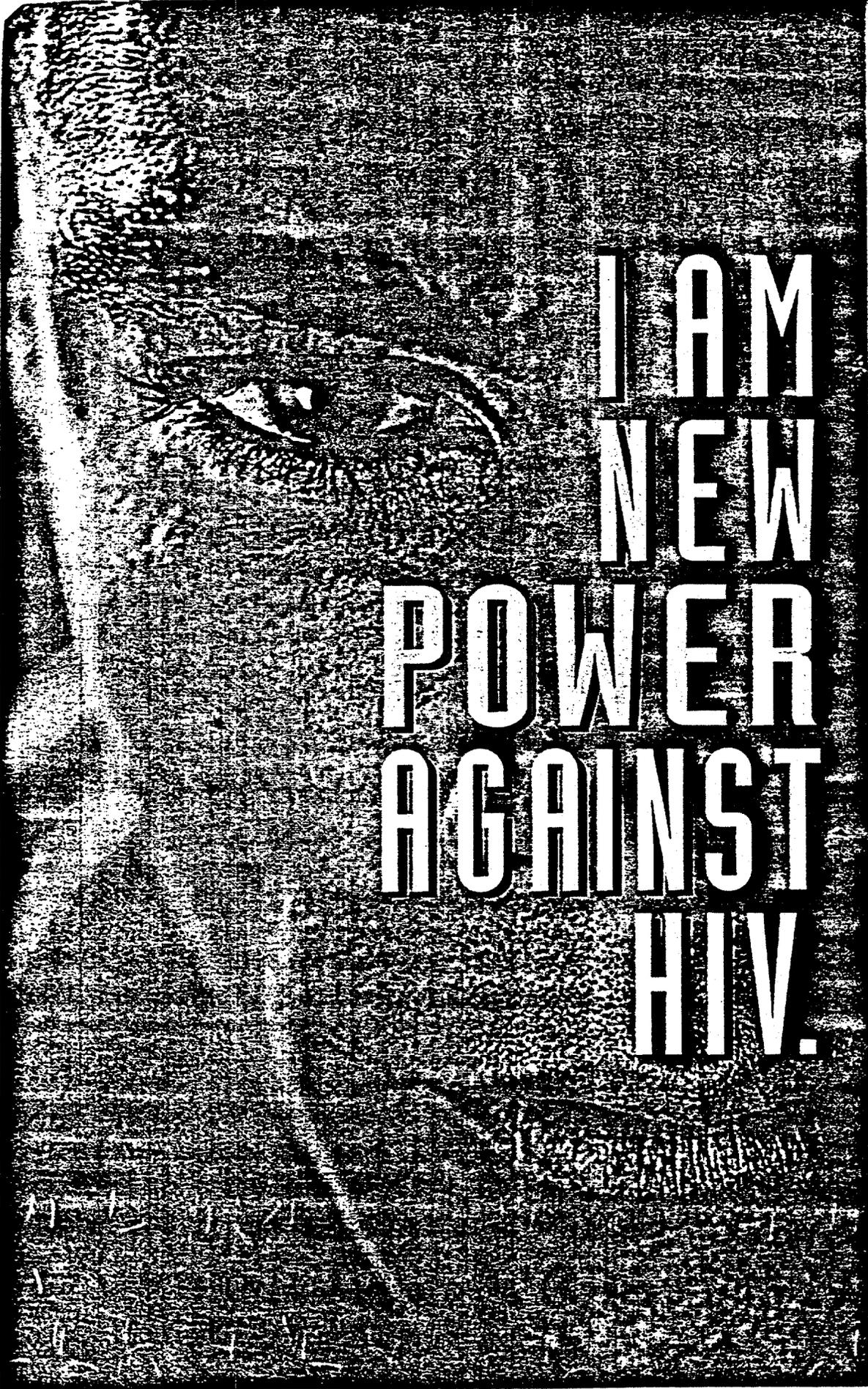
new for **HIV**



**I AM
HERE**

GlaxoWellcome





**I AM
NEW
POWER
AGAINST
HIV.**

Med Guide Box
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13-16

Talk to your healthcare professional about ZIAGEN. Or call 1-888-XXX-XXXX.

I am new

ZIAGENTM

abacavir sulfate 300 mg tablets

I am unique

ZIAGEN is a powerful new anti-HIV drug—the first guanosine nucleoside analogue for use in combination therapy.

I drive down viral load

Most people who took ZIAGEN as part of their first combination therapy achieved undetectable viral load at 16 weeks—without taking a protease inhibitor.* It's not known whether taking ZIAGEN will slow the progress of HIV disease or help you live longer.

I am two pills a day, with or without food

The easy dosing of ZIAGEN—just one tablet in the morning and one at night, with or without food—simplifies your combination therapy.

I give you new treatment options

ZIAGEN is powerful enough to achieve undetectable viral load when used in initial combination therapy*—for example, ZIAGEN + COMBIVIR® (lamivudine 150 mg/zidovudine 300 mg) Tablets—and may preserve future treatment options. ZIAGEN can be effective in patients who have used anti-HIV drugs before, but the effects may be less.

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, STOP TAKING ZIAGEN AND CALL YOUR DOCTOR IMMEDIATELY: fever; nausea, vomiting, diarrhea, or abdominal pain; severe tiredness, run-down feeling, achiness, or generally ill feeling; skin rash (redness and/or itching). 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.

A buildup of lactic acid and an enlarged liver, including fatal cases, have been reported rarely with HIV drugs of this type.

The most common side effects were nausea, headache, tiredness, and nausea and vomiting.

52-54

168
Figure 1
23-25

389-390

168
Figure 1

211-213

329-332
Table 1

*Of all patients taking ZIAGEN with lamivudine + zidovudine in this clinical trial, including those who did not complete their therapy, 79% had viral load undetectable below 400 copies/mL.

Please see important information in the Medication Guide for ZIAGEN on adjacent page.



ABC078

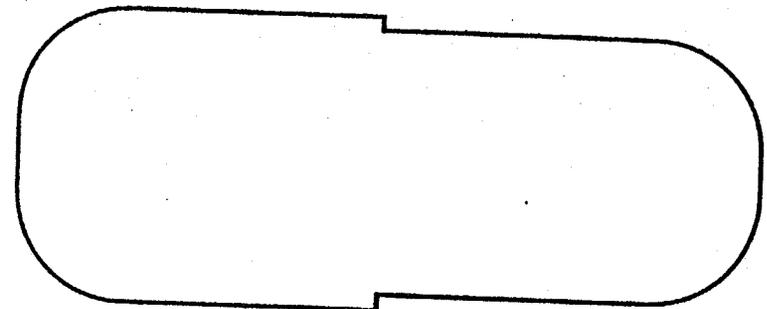
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Important: New HIV Product Information

Ziagen[™]
abacavir sulfate

Full Prescribing Information Enclosed



NEW ZIAGEN Safety Profile

Generally well tolerated in clinical trials

Most common clinical adverse events in therapy-naive adults

PI Lines
331-332

Adverse Event	Clinical Adverse Events (≥ 5% Frequency) In Therapy-Naive Adults (CNA3003)			
	All Events		Severe Events (grade 3/4)	
	ZIAGEN+3TC+ AZT (n=83)	3TC+AZT (n=81)	ZIAGEN+3TC+ AZT (n=83)	3TC+AZT (n=81)
Body as a whole				
Headache	31%	20%	2%	2%
Malaise and fatigue	34%	25%	0%	0%
Digestive				
Nausea	47%	41%	2%	2%
Diarrhea	12%	11%	0%	0%
Nausea and vomiting	16%	11%	2%	1%
Loss of appetite/anorexia	11%	10%	0%	0%
Nervous system				
Insomnia and other sleep disorders	7%	5%	0%	0%
Musculoskeletal				
Musculoskeletal pain	7%	5%	0%	0%

335-342

- Laboratory abnormalities occurred infrequently and were similar in both treatment arms (neutropenia, elevated creatine phosphokinase, and elevated triglycerides)

Important safety information

16-18

Lactic acidosis and severe hepatomegaly with steatosis, including fatal cases, have been reported with the use of nucleoside analogues, alone or in combination, including ZIAGEN and other antiretrovirals.

I drive down viral load. I am two pills a day, with or without food. I have n

Hypersensitivity Reaction *PI Lines 302-321*

Incidence

- 3% to 5% of patients receiving ZIAGEN in clinical studies

Multiorgan/body system involvement

- Frequently observed signs and symptoms include fever, skin rash, fatigue and gastrointestinal symptoms such as nausea, vomiting, diarrhea, or abdominal pain
- Other signs and symptoms may include malaise, lethargy, myalgia, arthralgia, edema, shortness of breath, paresthesia; physical findings may include lymphadenopathy, mucous membrane lesions (conjunctivitis and mouth ulcerations), and rash (usually maculopapular or urticarial)
—hypersensitivity reactions may occur without rash

- Laboratory abnormalities include elevated liver function tests, increased creatine phosphokinase or creatinine, and lymphopenia
- Anaphylaxis, liver failure, renal failure, hypotension, and death have occurred in association with hypersensitivity reactions

Onset and duration

- Symptoms usually appear within first 6 weeks of treatment, although these reactions may occur at any time during therapy
—worsen with continued therapy and usually resolve upon discontinuation of ZIAGEN

Management

- Patients developing signs or symptoms of hypersensitivity should discontinue treatment as soon as hypersensitivity reaction is first suspected, and should seek medical evaluation immediately
- 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

I am power against HIV

^{-new}
ZiagenTM
abacavir sulfate ³⁰⁰mg
ONE TABLET BID

Significant P450 drug interactions. I help protect future options.



A powerful NRTI offers new options

Resistance profile

Lack of cross-resistance between classes may preserve treatment options

PI Lines

82-85

- Cross-resistance between ZIAGEN and protease inhibitors is unlikely because enzyme targets are different; cross-resistance between ZIAGEN and nonnucleoside reverse transcriptase inhibitors is also unlikely

Mutations found in isolates from patients treated with ZIAGEN

71-73

- K65R, L74V, Y115F, and M184V

74-76

- Phenotypic analysis of isolates that harbor mutations associated with ZIAGEN from 17 patients after 12 weeks of monotherapy with ZIAGEN exhibited a 3-fold decrease in susceptibility in vitro

76-77

- The clinical relevance of genotypic and phenotypic changes associated with therapy with ZIAGEN has not been established



Efficacy in treatment-experienced patients demonstrated in pediatric trial

175-184

- In a placebo-controlled study, efficacy and safety of ZIAGEN have been demonstrated in treatment-experienced children

186-192

—ZIAGEN in combination with lamivudine + zidovudine provided significant decrease in viral load and increase in CD4 cell count when compared to treatment with lamivudine + zidovudine

Study Reports

QAA 2003

CNAB 3009

222-225

- Supportive trials in treatment-experienced adults have shown similar results
- In clinical trials, patients with uncontrolled viral replication following prolonged prior zidovudine and lamivudine exposure who had HIV-1 isolates that contained multiple mutations conferring resistance to NRTIs showed minimal response to the addition of ZIAGEN as a single new agent



I drive down viral load. I am two pills a day, with or without food. I have n



fC HIV therapy

Convenient dosing encourages adherence

PI Lines

389

- Adults: One 300-mg tablet BID, in combination with other HIV medications
- Children 3 months to 16 years of age: 8 mg/kg BID, not to exceed 300 mg BID, in combination with other HIV medications

391-393

No dietary restrictions

- ZIAGEN can be dosed with or without food for both adults and children

388

2 scripts

I am power against HIV ^{- new}
ZiagenTM
abacavir sulfate _{300 mg}
ONE TABLET BID

significant P450 drug interactions. I help protect future options.

NEW ZIAGEN

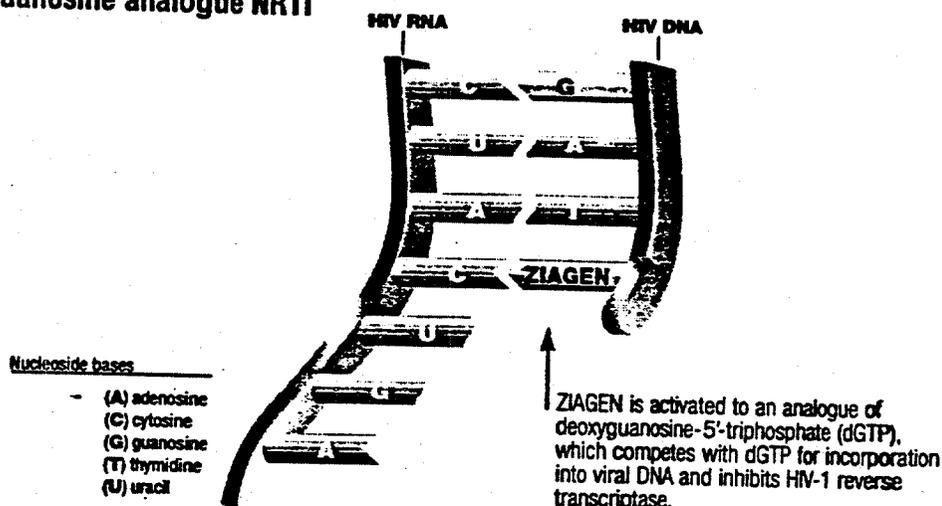
A powerful NRTI offers new of On

Unique in its class

The first guanosine analogue NRTI

PI Lines

52-56



Faletto p.1102

Anabolic pathway

- Does not require thymidine kinase for activation¹

In vitro activity with other antiretrovirals

- Synergistic in combination with amprenavir,* AZT, and nevirapine; additive in combination with 3TC[®], ddC, ddl, and d4T

Significant P450 drug interactions unlikely

- ZIAGEN is not significantly metabolized by the cytochrome P450 enzyme system
- clinically significant drug interactions are unlikely to occur between ZIAGEN and drugs metabolized through this system

Penetration of cerebrospinal fluid

- CSF AUC_(0-6h) to plasma AUC_(0-6h) ratio ranged from 27% to 33% (n=3)

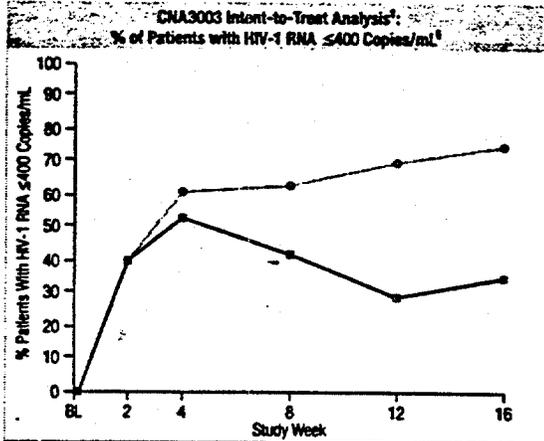
*An investigational protease inhibitor currently available through early access.

I drive down viral load. I am two pills a day, with or without food. I have

HIV therapy

75% undetectable (≤ 400 copies/mL) with a triple-NRTI combination

Trial CNA3003: ZIAGEN + 3TC + AZT[†] in therapy-naive patients



A prospective, randomized, double-blind, multicenter trial in 173 therapy-naive adults with a median CD4 cell count of 450 cells/mm³ and median plasma HIV-1 RNA of 31,623 copies/mL (approximately 4.5 log₁₀ copies/mL). Treatment with ZIAGEN + lamivudine (3TC) + zidovudine (AZT) was compared to treatment with lamivudine + zidovudine[†] alone; 48-week study with planned interim analysis at 16 weeks.[‡]

PI Lines

157-166

Study 3003 p.4

- At week 16, 75% (65/87) of patients receiving ZIAGEN + lamivudine + zidovudine had plasma HIV-1 RNA levels ≤ 400 copies/mL compared with 35% (30/86) receiving lamivudine + zidovudine alone ($P < 0.0001$)[‡]
- Through 16 weeks of therapy the median CD4 changes from baseline were 47 cells/mm³ in the group receiving ZIAGEN and 112 cells/mm³ in the control group; this difference was not statistically significant

Study 3003 Table 7
+
p. 121

PI lines 171-172

Additional trial in therapy-naive patients

- Preliminary findings from a second controlled study using ZIAGEN + Combivir[®] (lamivudine 150 mg/zidovudine 300 mg) in therapy-naive adults were supportive of the efficacy of ZIAGEN

173-174

[†]Lamivudine and zidovudine are now combined in one tablet: Combivir[®] (lamivudine 150 mg/zidovudine 300 mg) Tablets.

[‡]Intent-to-treat analysis includes all patients who were randomized, regardless of whether or not they completed study medication. Patients who stopped drug for any reason were counted as failures.

[§]Roche Amplicor HIV-1 MONITOR[®] Test.

I am power against HIV ^{new}
Ziagen[™]
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