ZIAGEN® (Abacavir)

Effective Date: 7/24/12
Date Developed: 7/3/12 by Albert Reeves MD
Last Approval Date: 1/26/16, 1/24/17, 1/23/18, 1/22/19, 2/18/20

ZIAGEN® is an Antiretroviral Agent, Reverse Transcriptase Inhibitor (Nucleoside)

**Pre-Authorization Criteria:**

VCHCP will authorize ZIAGEN® for FDA indicated treatment of HIV infections in combination with other antiretroviral agents.

ZIAGEN® is one of multiple products containing abacavir. Before starting ZIAGEN, review medical history for prior exposure to any abacavir-containing product in order to avoid reintroduction in a patient with a history of hypersensitivity to abacavir.

VCHCP requires that ZIAGEN be prescribed by an Infectious Disease specialist or HIV credentialed provider.

**Dosing: Adult**

**HIV treatment:** Oral: 300 mg twice daily or 600 mg once daily in combination with other antiretroviral agents

**Dosing: Pediatric**

**HIV treatment:** Oral:

Infants, Children, and Adolescents 3 months to <16 years: 8 mg/kg body weight twice daily (maximum: 300 mg twice daily) in combination with other antiretroviral agents. **Note:** May consider 16 to 20 mg/kg once daily dosing (maximum: 600 mg/day) in stable patients with undetectable viral load and stable CD4 count for more than 6 months (HHS [pediatric], 2014)

U.S. manufacturer labeling: Alternative dosing to be considered for pediatric patients ≥14 kg who are able to swallow tablets:

14 to 21 kg: 150 mg (½ tablet) twice daily
>21 kg to <30 kg: 150 mg (1/2 tablet) in the morning and 300 mg (1 tablet) in the evening
≥30 kg: 300 mg (1 tablet) twice daily

Adolescents ≥16 years: 300 mg twice daily or 600 mg once daily. **Note:** For patients who are HLA-B*5701 negative, abacavir is a component of a recommended regimen (with dolutegravir and lamivudine) for all treatment-naïve patients and a component of a recommended regimen (with efavirenz and lamivudine or with ritonavir boosted atazanavir and lamivudine) in treatment-naïve patients with pre-ART plasma HIV RNA <100,000 copies/mL (HHS [adult], 2014; HHS [pediatric], 2014).

**Dosage Forms: U.S.**

**Solution, oral:**

Ziagen®: 20 mg/mL (240 mL [DSC]) [strawberry-banana flavor]

Ziagen®: 20 mg/mL (240 mL) [contains propylene glycol; strawberry-banana flavor]

**Tablet, oral:**

Ziagen®: 300 mg [DSC]

Ziagen®: 300 mg [scored]

**Warnings/Precautions**

**Contraindications:**

ZIAGEN® (abacvir sulfate) tablets and oral solution are contraindicated in patients:

- With previously demonstrated hypersensitivity to abacavir, or any of the other components of the product (see WARNINGS AND PRECAUTIONS, and DOSAGE FORMS, COMPOSITION AND PACKAGING SECTIONS).
- With moderate or severe hepatic impairment since the pharmacokinetics have not been studied in this patient group.

**Boxed warnings:**

- Hypersensitivity reactions: Serious and sometimes fatal hypersensitivity reactions have been associated with abacavir therapy. Hypersensitivity to abacavir is a multiorgan clinical syndrome usually characterized by a sign or symptom in 2 or
more of the following groups:
- constitutional, including achiness, fatigue, or generalized malaise
- fever
- GI, including abdominal pain, diarrhea, nausea, or vomiting
- rash
- respiratory, including cough, dyspnea, or pharyngitis

• Lactic acidosis/hepatomegaly: Lactic acidosis and severe hepatomegaly with steatosis, including fatal cases, have been reported with the use of nucleoside analogs alone or in combination, including abacavir and other antiretrovirals.

REFERENCES

1. DHHS Panel on Antiretroviral Guidelines for Adults and Adolescents, “Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents, Department of Health and Human Services,” March 27, 2012;1-239. Available at http://www.aidsinfo.nih.gov


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Date Reviewed/No Updates: 2/18/20 by H. Taekman, MD; R. Sterling, MD  
Date Approved by P&T Committee: 2/18/20

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