Lactic Acidosis/Hepatomegaly With Steatosis

lamivudine/zidovudine tablets co-packaged with abacavir tablets should be discontinued.

5.3 Lactic Acidosis/Hepatomegaly With Steatosis

Tablets: Scored lamivudine/zidovudine 150 mg/300 mg, and scored abacavir 300 mg (3)

by granulocyte count <1,000 cells/mm$^3$ or hemoglobin <9.5 g/dL

Lamivudine/Zidovudine Tablets USP 150 mg/300 mg Co-Packaged with Abacavir Tablets USP 300 mg are nucleoside analogues,

----------------------------------------------------------INDICATIONS AND USAGE---------------------------------------------------------

Co-package:
capsule shaped, biconvex, film-coated tablets with deep breakline in between 'C' and '60' on one side and deep breakline on the

Lamivudine and Zidovudine Tablets,

3 DOSAGE FORMS AND STRENGTHS

The lamivudine/zidovudine tablets co-packaged with abacavir tablets are not recommended for patients with impaired renal

HIGHLIGHTS OF PRESCRIBING INFORMATION

• Hematologic toxicity including neutropenia and anemia have been associated with the use of zidovudine,

• Hypersensitivity Reactions: Serious and sometimes fatal hypersensitivity reactions have been associated with

Hematologic Toxicity: Zidovudine, one of the 2 active ingredients in lamivudine and zidovudine tablets, has been

5.1 Hemotologic Toxicity/Bone Marrow Suppression

An increased risk of hepatotoxicity may occur in patients treated with zidovudine in combination with didanosine and hydroyurea

8.6      Renal Impairment

• Symptomatic myopathy

Pharma Code : 25950

your healthcare provider about your medical

take lamivudine, one of the medicines in

Abacavir sulfate one of the medications in

Lamivudine, Zidovudine, and/or Abacavir:

Mycobacterium avium

3% of 325 patients in the zidovudine group.

19%

ALT (>5 x ULN) 16 (6%) 16 (6%)

W506 0.6

Card your pharmacist gives you.

If you take abacavir sulfate or any other

Zalcitabine:

12%

Body as a Whole: Back pain, chest pain, flu-like syndrome, generalized pain, redistribution/accumulation of body fat

Lamivudine/Zidovudine Tablets Co-Packaged with Abacavir Tablets contain 3 nucleoside analogues: abacavir, lamivudine, and

1-infected patients receiving methadone-maintenance therapy with 600 mg of abacavir sulfate twice daily (twice the currently

12.1 Mechanism of Action

Abacavir sulfate is the enantiomer with

300 mg of abacavir as active ingredient and the following inactive ingredients: colloidal silicon dioxide, magnesium stearate,

300 mg of abacavir as active ingredient and the following inactive ingredients: colloidal silicon dioxide, magnesium stearate,

microcrystalline cellulose, and sodium starch glycolate. The tablets are coated with a film that is made of hypromellose, iron oxide

microcrystalline cellulose, and sodium starch glycolate. The tablets are coated with a film that is made of hypromellose, iron oxide

8.1 Pregnancy

Antiretroviral Pregnancy Registry:

8.2 Lactation

12 CLINICAL PHARMACOLOGY

Abacavir sulfate one of the medications in

Lamivudine/Zidovudine Tablets Co-Packaged with Abacavir Tablets do not

Do not take lamivudine/zidovudine tablets co-

healthcare provider if you:

• you have a fast or irregular heartbeat

• you don't feel like eating food for several

• you have had a previous reaction to any of the ingredients in lamivudine/zidovudine tablets co-packaged with

• you have any of the following:

Precautions (5.3)

NO

H SO

symptoms of lactic acidosis:

symptoms of liver problems:

12 CLINICAL PHARMACOLOGY

14 18 6 2 2 4

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17.09.2013 & 04.15 PM

USA (APL)

Submission

Packaged with Abacavir Tablets do not

Do not take lamivudine/zidovudine tablets co-

healthcare provider if you:

• you have a fast or irregular heartbeat

• you don't feel like eating food for several

• you have had a previous reaction to any of the ingredients in lamivudine/zidovudine tablets co-packaged with

• you have any of the following:

Precautions (5.3)

NO

H SO

symptoms of lactic acidosis:

symptoms of liver problems:
nevirapine, and the protease inhibitor (PI) amprenavir; and additive activity in combination with the NRTIs didanosine, Abacavir:

Lamivudine:

We do not know if abacavir can confer resistance to abacavir, didanosine, emtricitabine, lamivudine, stavudine, tenofovir, and zalcitabine; the L74V mutation Isolates containing abacavir resistance-associated mutations, namely, K65R, L74V, Y115F, and M184V, exhibited similar HBV mutants have been reported in HIV-infected patients who received lamivudine-containing antiretroviral regimens in

Lamivudine, 53/554 (10%) patients were identified as virological failures (plasma HIV-1 RNA level 400 copies/mL) by Week 48. Of patients treated with lamivudine alone or in combination with zidovudine, isolates have emerged with a substitution at codon 184, which
dual resistance required the presence of multiple amino acid substitutions, the most essential of which may

Tooth Whitening: Do not use it near your gums, eyes, or other sensitive areas. Avoid direct contact with your eyes. Do not wash out with water after you use it. Do not place it in your mouth for any length of time. Do not use it in the mouth if you have difficulty breathing. Do not use it if you have any breathing problems. Do not use it if you have a history of any breathing problems. Do not use it if you have a history of any allergies. Do not use it if you have a history of any heart problems. Do not use it if you have a history of any kidney problems. Do not use it if you have a history of any liver problems. Do not use it if you have a history of any other medical problems.

Special Populations:

Due to the common metabolic pathways of abacavir and zidovudine via glucuronyl transferase, 15 HIV-infected


cellular DNA polymerases

Drug and Dose

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