The recommended dosage of abacavir tablets for adults is 600 mg daily, administered orally as either 300 mg or any other abacavir-containing product. Use of the 300 mg dose is favored in patients who have a history of nausea or in whom it is desired to minimize the drug levels by reducing the amount of drug administered. Other abacavir-containing products may be used in combination with abacavir tablets.

Abacavir tablets USP 300 mg in combination with other antiretroviral agents, are indicated for the treatment of HIV-1 infection in adults and pediatric subjects aged 12 years and older with documented failure of and intolerance to one or more antiretroviral therapy regimens containing a nucleoside reverse transcriptase inhibitor, is indicated in combination with other antiretroviral agents.

Similar severe reactions have also occurred rarely following the reintroduction of abacavir-containing products into treatment, and therefore the reintroduction of abacavir-containing products must be closely monitored. Whether and when to discontinue abacavir-containing products depends on the specific circumstances of the patient and the nature and severity of the adverse reaction.

Patients who carry the HLA-B*5701 allele. (4) HLA-B*5701 has been associated with a high risk of hypersensitivity reactions to abacavir. Therefore, patients with a history of a severe hypersensitivity reaction to abacavir should not use abacavir tablets and should be closely monitored for an initial reaction when re-exposed to abacavir tablets. The presence of HLA-B*5701 allele is strongly predictive of the risk of hypersensitivity reactions. (4) Patients with Hepatic Impairment: Mild hepatic impairment (Child-Pugh A) does not require dosage adjustment. (5) Aminotransferase levels should be monitored before and during therapy. (5) Patients with a history of renal impairment are at risk for drug accumulation if dosed at the full 600 mg daily dose. 

Adverse Reaction

Drug hypersensitivity 9% <1%b

Overdosage

Abacavir is not expected to cause serious toxicity when accidentally ingested in high doses. If overdose occurs, it may be managed by supportive measures."

Clinical Trials Experience in Pediatric Subjects

In CNA30024, a study of 150 pediatric subjects aged 2-18 years with advanced HIV-1 infection who were randomized from a treatment-naive cohort to receive either abacavir plus lamivudine plus efavirenz or abacavir plus lamivudine plus indinavir, the incidence of treatment-emergent adverse reactions of at least moderate intensity (Grades 2-4) were generally comparable between the two treatment arms. Comparing treatment-emergent adverse reactions of at least moderate intensity (Grades 2-4) for the abacavir plus lamivudine plus efavirenz arm and the abacavir plus lamivudine plus indinavir arm revealed no significant differences in the incidence of treatment-emergent adverse reactions of at least moderate intensity (Grades 2-4) and no statistically significant differences in the incidence of discontinuations due to adverse reactions. The treatment-emergent adverse reaction rates were generally comparable between the two treatment arms. The most common treatment-emergent adverse reactions (≥25%) were rash (27%) and diarrhea (21%). The most common treatment-emergent adverse reactions (≥2% and >1%) were rash (21%), diarrhea (12%), neutropenia (10%), hypertriglyceridemia (10%), and elevated ALP (10%).

The most common laboratory abnormalities of Grade 3 were elevated AST, ALT, ALP and bilirubin (5%). The most common laboratory abnormalities of Grade 4 were hypertriglyceridemia (5%) and elevated AST, ALT, ALP and bilirubin (5%).

The most common treatment-emergent adverse reactions of at least moderate intensity (Grades 2-4) were generally comparable between the two treatment arms. Comparing treatment-emergent adverse reactions of at least moderate intensity (Grades 2-4) for the abacavir plus lamivudine plus efavirenz arm and the abacavir plus lamivudine plus indinavir arm revealed no significant differences in the incidence of treatment-emergent adverse reactions of at least moderate intensity (Grades 2-4) and no statistically significant differences in the incidence of discontinuations due to adverse reactions. The treatment-emergent adverse reaction rates were generally comparable between the two treatment arms. The most common treatment-emergent adverse reactions (≥25%) were rash (27%) and diarrhea (21%). The most common treatment-emergent adverse reactions (≥2% and >1%) were rash (21%), diarrhea (12%), neutropenia (10%), hypertriglyceridemia (10%), and elevated ALP (10%).

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ARTWORK DETAIL LABEL

Product: Abacavir Tablets USP 300 mg
Buyer/Country: STRIDES PHARMA INC - US
Dimension: 416 x 320mm with Perforation as indicated.
New Item Code: 1037423
Colour Shades: BLACK
Change Ctrl/No.: PIC-0010I57001 Record Number: 203867
Design/Style: Front & Back Printing. To be supplied in finished size of 62x32mm x 28.5mm
Substrate: 480/-45 GSM Paper
Special Instructions: PRINTING CLARITY TO BE CLEAR AND SHARP.
Auto-Registration Requirements: NA

Caution to the printer: Before processing, please ensure that the ARTWORK received for printing is exactly as listed in the APPROVED ARTWORK provided to you. No change of your design or any other aspect of abacavir tablets without writing to your healthcare provider. You may also be asked to obtain written instructions fromyour healthcare provider. You may also be asked to obtain written instructions from your healthcare provider.
Side effects to FDA at 1-800-FDA-1088.

Abacavir tablets can cause serious side effects including:

- rash (discontinue abacavir tablets right away if you have any of the following signs of a rash):
  - a red, itchy rash that gets worse or affects a large part of your body
  - small blisters or skin peeling
  - itching that is not relieved by a bath or shower
  - facial swelling
  - facial peeling
  - eye swelling
  - eye peeling
  - oozing from your mouth, nose, or ears
  - skin peeling or shedding

- fever
- abdominal pain
- unusual bleeding
- pancreatitis
- tremors
- trouble swallowing
- difficulty breathing
- confusion
- numbness
- weakness
- changes in color of your skin, lips, or nails
- vision changes

Tell your healthcare provider if you have any side effects that bother you or if you think you might have a serious reaction.

Revised: 04/2019

Product
Abacavir Tablets 300 mg

Buyer/Country
STREX PHARMA INC - US

Component
Outsider with medication Guide

Dimension
416 x 589mm with Perforation as indicated.

New Item Code
1007423

Old Item Code
1051642

Pack
NA

Change Control No.
PC-01515/0000/01

Record Number
2028870

No. of Colours
1

Artwork Version
5.0

Colour Shades
BLACK

Design Style
Front & Back Printing. To be supplied in finished size of 52mm x 62.5mm

Substrate
40/40 GSM Paper

Special Instructions
PRINTING QUALITY TO BE CLEAR AND SHARP.

A4

Note

When ordering artwork, please ensure that you include the artwork received for printing is ready in the with APPROVED ARTWORK provided to you. In case of any FOQRSTING and/or Printing it with the APPROVED ARTWORK, please inform POC for further action. DO NOT MAKE ANY CHANGE TO THE ARTWORK WITHOUT WRITTEN INSTRUCTIONS FROM POC.

Perforation required