Avilam®

Tablet

Description

Avilam (formerly known as 3TC) is the brand name for Lamivudine, a synthetic nucleoside analogue with activity against HIV.

Indications

Avilam in combination with Zidovudine is indicated for the treatment of HIV infection.

Dosage and Administration

Adults and adolescents (12 to 16 years) : The recommended oral dose of Avilam for adults and adolescents is 150 mg twice daily administered in combination with Zidovudine. For adults with low body weights (less than 50 kg or 110 lb), the recommended oral dose of Avilam is 2 mg/kg twice daily administered in combination with Zidovudine. No data are available to support a dosage recommendation for adolescents with low body weight (less than 50 kg).

Paediatric patients : The recommended oral dose of Avilam for paediatric patients of age between 3 months to up to 12 years is 4 mg/kg twice daily (up to a maximum of 150 mg twice a day) administered in combination with Zidovudine.

Dose adjustment : It is recommended that doses of Avilam be adjusted in accordance with renal function in patients older than age 16 years (see following table). Insufficient data are available to recommend a dosage of Avilam in patients undergoing dialysis.

Contraindications

Avilam is contraindicated in patients with previously demonstrated clinically significant hypersensitivity to any of the components of the product.

Precautions

In paediatric patients with a history of pancreatitis or other significant risk factors for the development of pancreatitis, the combination of

Table 1 : Adjustment of Dosage of Avilam in Accordance with Creatinine Clearance

Creatinine Clearance (ml/min)	Recommended Dosage of Avilam
> 50	150 mg twice daily
30 - 49	150 mg once daily
15 - 29	150 mg first dose, then 100 mg once daily
5 - 14	150 mg first dose, then 50 mg once daily
< 5	50 mg first dose, then 25 mg once daily

Avilam and Zidovudine should be used with extreme caution and only if there is no satisfactory alternative therapy. Treatment with Avilam should be stopped immediately if there are clinical signs, symptoms, or laboratory abnormalities suggestive of pancreatitis.

Lactic acidosis and severe hepatomegaly with steatosis, including fatal cases, have been reported with the use of antiretroviral nucleoside analogues alone or in combination, including Lamivudine. A majority of these cases have been in women. Caution should be exercised when administering Avilam to any patient, and particularly to those with known risk factors for liver disease. Treatment with Avilam should be suspended in any patient who develops clinical or laboratory findings suggestive of lactic acidosis or hepatotoxicity. Reduction of the dosage of Avilam is recommended for patients with impaired renal function.

In clinical trials and post-marketing experience, some patients with HIV infection who have chronic liver disease due to hepatitis B virus infection experienced clinical or laboratory evidence of recurrent hepatitis upon discontinuation of Lamivudine. Consequences may be more severe in patients with decompensated liver disease.

Side Effects

Adults : Selected clinical adverse events with a > 5% frequency during therapy with Lamivudine 150 mg bid plus Zidovudine 200 mg tid compared with Zidovudine are listed in the following table 2.

Use in Special Populations

Pregnancy : Animal reproductive toxicity studies are not always predictive of human response. There are no adequate and well controlled studies in pregnant women. Lamivudine should be used during pregnancy only if the potential benefits outweigh the risks.

Lactation : The US Public Health Service Centers for Disease Control and Prevention recommend that HIV-infected mothers should not breast feed their infants to avoid the risk of postnatal transmission of HIV infection.

Table 2 : Selected Clinical Adverse Events (> 5% Frequency) in Four Controlled Clinical Trials

Adverse Event	Lamivudine 150 mg bid plus Zidovudine (n = 251)	Zidovudine (n = 230)
General		
Headache	35 %	27 %
Malaise and fatigue	27 %	23 %
Fever or chills	10 %	12 %
Digestive		
Nausea and vomiting	33 %	29%
Diarrhoea	18 %	22%
Anorexia and/or decreased appetite	10%	7%
Abdominal pain	9%	11%
Abdominal cramps	6%	3%
Dyspepsia	5%	5%
Nervous system		
Neuropathy	12%	10%
Insomnia and other sleep disorders	11%	7%
Dizziness	10%	4%
Depressive disorders	9%	4%
Respiratory		
Nasal signs and symptoms	20%	11%
Cough	18%	13%
Skin		
Skin rashes	9%	6%
Musculoskeletal		
Musculoskeletal pain	12%	10%
Myalgia	8%	6%
Arthralgia	5%	5%

Observed During Clinical Practice :
The events identified during use of the drug in clinical practice include alopecia, anaphylaxis, hyperglycaemia, lactic acidosis and hepatic steatosis, peripheral neuropathy, pruritus, rash, urticaria, and weakness.

Commercial Pack

Avilam® Tablet : Each box contains 1 x 10's tablets in blister strip. Each tablet contains Lamivudine INN 150 mg.