Entavir

Tablet

DRUG INTERNATIONAL LTD.

Composition : Entavir-0.5 : Each Film Coated Tablet contains Entecavir USP 0.5mg.

Entavir-1 : Each Film Coated Tablet contains Entecavir USP 1mg.

Pharmacology : Entecavir is an antiviral drug against hepatitis B virus. Following oral administration in healthy subjects, entecavir peak plasma concentrations occurred between 0.5 and 1.5 hours. Based on the pharmacokinetic profile of entecavir after oral dosing, the estimated apparent volume of distribution is in excess of total body water, suggesting that entecavir is extensively distributed into tissues. Binding of entecavir to human serum proteins in vitro was approximately 13%. Entecavir is predominantly eliminated by the kidney with urinary recovery of unchanged drug at steady state ranging from 62% to 73% of the administered dose.

Indications : This tablet is indicated for the treatment of chronic hepatitis B virus infection in adults with evidence of active viral replication and either evidence of persistent elevations in serum aminotransferases or histologically active disease.

Dosage and administration : The recommended dose of Entecavir for chronic hepatitis B virus infection in nucleoside-treatment-naive adults and adolescents 16 years of age and older is 0.5mg once daily. The recommended dose of Entecavir in adults and adolescents (>16 years of age) with a history of hepatitis B viremia while receiving lamivudine is 1mg once daily. Entecavir should be administered on an empty stomach (at least 2 hours after a meal and 2 hours before the next meal). Or, as directed by the registered physician.

Contraindication : It is contraindicated in patients with known hypersensitivity to any component of this drug.

Precaution : Renal Impairment : Dosage adjustment of Entecavir is recommended for patients with a creatinine clearance<50ml/min, including patients on hemodialysis. Hepatic Impairment : No dosage adjustment is necessary for patients with hepatic impairment.

Side effects : The most common side effects of Entecavir treated patients were headache, fatigue, dizziness and nausea.

Use in pregnancy and lactation : Entecavir should be used during pregnancy only if clearly needed and after careful consideration of the risks and benefits. It is not known whether this drug is excreted in human milk. Mothers should be instructed not to breast-feed if they are taking Entecavir.

Use in Child : There is no data available.

Drug Interaction : Coadministered drug were not altered in interaction studies of Entecavir with lamivudine, adefovir dipivoxil, and tenofovir disoproxil fumarate.

Overdose : If overdose occurs, the patient must be monitored for evidence of toxicity and standard supportive treatment applied as necessary.

Storage : Store below 30°C in a dry place.

Packing : Entavir-0.5 : Each box contains 1x 14's tablets in blister pack.

Entavir-1 : Each box contains 1x 14's tablets in blister pack.