Genevir

Entecavir tablet

Presentation

Genevir 0.5 mg Tablet: Each film coated tablet contains Entecavir BP 0.5 mg.
Genevir 1mg Tablet: Each film coated tablet contains Entecavir BP 1 mg.

Pharmacodynamic Properties

Entecavir, a guanosine nucleoside analogue with activity against HBV reverse transcriptase (DNA polymerase) by competing with the natural substrate deoxyguanosine triphosphate

Indications

Entecavir 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 (ALT or AST) or histologically active disease

Dosage and Administration

Entecavir should be administered on an empty stomach (at least 2 hours after a meal and 2 hours before the next meal).

Compensated Liver Disease

The recommended dose of Entecavir for chronic hepatitis B virus infection in adults, adolescents (at least 16 years of age) and older is 0.5 mg once daily.

The recommended dose of Entecavir in adults and adolescents (at least 16 years of age) with a history of hepatitis B viremia while receiving lamivudine or known lamivudine resistance mutations 1 mg once daily.

Decompensated Liver Disease

The recommended dose of Entecavir for chronic hepatitis B virus infection in adults with decompensated liver disease is 1 mg once daily.

Renal Impairment

Dosage adjustment is recommended for patients with creatinine clearance less than 50 ml/min, including patients on hemodialysis or continuous ambulatory peritoneal dialysis (CAPD), as shown below -

Creatinine Clearance (ml/min)	Usual Dose (0.5 mg)
≥ 50	0.5 mg once daily
30 to < 50	0.5 mg every 48 hours
10 to <30	0.5 mg every 72 hours
< 10, Haemodialysis or CAPD	0.5 mg every 7 days

Contraindications

Entecavir is contraindicated in patients with previously demonstrated hypersensitivity to Entecavir or any component of the product

Side Effects

The most common side effects are –
Muscle pain or weakness, trouble breathing, stomach pain, nausea with vomiting, low fever, loss of appetite, jaundice (yellowing of the skin or eyes) etc.

Precaution

Dosage adjustment is recommended in renal dysfunction (CrCl <50ml/min), including patients on hemodialysis or CAPD. May require HIV antibody testing prior to treatment. Caution with known risk factors for liver disease. D/C if lactic acidosis or pronounced hepatotoxicity occurs. Caution with dose selection in elderly.

Drug Interaction

May increase levels of either Entecavir or concomitant drugs that reduce renal function or compete for active tubular secretion; closely monitor for adverse events

Pregnancy & Lactation

Category C. Entecavir should be used during pregnancy only if clearly needed and after careful consideration of the risks and benefits. It is not known whether Entecavir is excreated in breast milk. Mothers should be instructed not to breast feed if they are taking Entecavir.

Overdosage

There is limited experience of Entecavir overdosage reported in patients. Healthy subjects who received single entecavir doses up to 40 mg or multiple doses up to 20 mg/day for up to 14 days had no increase in or unexpected adverse events. If overdose occurs, the patient must be monitored for evidence of toxicity, and standard supportive treatment applied as necessary. Following a single 1 mg dose of Entecavir, a 4-hour hemodialysis session removed approximately 13% of the entecavir dose.

Storage Conditions

Store in a cool (below 30°C) & dry place, away from light. Keep out of reach of children.

Commercial Pack

Genevir 0.5 mg Tablet: Each Box containing 1 blister pack of 10 tablets.
Genevir 1 mg Tablet: Each Box containing 1 blister pack of 10 tablets.

Manufactured by :
general **GENERAL**
Pharmaceuticals Ltd.
Kaliakair, Gazipur, Bangladesh

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