Cavir™

Entecavir

COMPOSITION
Cavir™ 0.5 Tablet: Each film coated tablet contains Entecavir INN 0.5 mg.
Cavir™ 1 Tablet: Each film coated tablet contains Entecavir INN 1 mg.

PHARMACOLOGY
Entecavir is a guanosine nucleoside analogue. It Inhibits hepatitis B virus (HBV) DNA polymerase (reverse transcriptase) by competing with the natural substrate deoxyguanosine triphosphate.

INDICATION
Cavir™ 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
Cavir™ should be administered on an empty stomach (at least 2 hours after a meal or 2 hours before the next meal).

Nucleoside-treatment-naive (≥16 years): 0.5 mg once daily.
Lamivudine-refractory or known lamivudine or telbivudine resistance mutations (≥16 years): 1 mg once daily.

Decompensated Liver Disease
Recommended dose 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-

Dosage of Entecavir in patients with renal impairment				
Creatinine clearance (ml/min)	> 50	30 to <50	10 to <30	<10, Hemodialysis or CAPD
Dose	0.5 mg every 24 hrs	0.5 mg every 48 hrs	0.5 mg every 72 hrs	0.5 mg every 7 days

CONTRAINDICATION
Entecavir is contraindicated in patients with known hypersensitivity to Entecavir or any component of the product.

PRECAUTION
Lactic acidosis: Lactic acidosis and severe hepatomegaly with steatosis, including fatal cases have been reported with the use of nucleoside analogues alone or in combination with antiretrovirals.

Exacerbations of hepatitis B after discontinuation of treatment: Severe acute exacerbations of hepatitis B have been reported in patients who have discontinued anti-hepatitis B therapy, including Entecavir .

USE IN PREGNANCY & LACTATION
Pregnancy: Pregnancy category C. There are no data on the effect of Entecavir on transmission of HBV from mother to infant. Therefore, appropriate care should be taken.

Lactation: It is not known whether Entecavir is excreted in breast milk. Mothers should be instructed not to breast feed if they are taking Entecavir .

PEDIATRIC USE
Safety and effectiveness of Entecavir in pediatric patients below the age of 16 years have not been established.

GERIATRIC USE
Clinical studies of Entecavir did not include sufficient numbers of subjects aged 65 years and over to determine whether they respond differently from younger subjects. But care should be taken in dose selection, and it may be useful to monitor renal function.

SIDE EFFECT
The most common side effects are headache, fatigue, dizziness and nausea.

DRUG INTERACTION
Coadministration of Entecavir with drugs that reduce renal function or compete for active tubular secretion may increase serum concentration of either Entecavir or the coadministered drug. Coadministration of Entecavir with Lamivudine, Adeforvir Dipivoxil, or Tenofovir Disoproxil Fumatare did not result significant drug interactions.

STORAGE
Store in a cool and dry place, protected from light and moisture. Keep the medicine out of the reach of children.

HOW SUPPLIED
Cavir™ 0.5 Tablet: Each box contains 5 tablets in Alu-Alu blister pack.
Cavir™ 1 Tablet: Each box contains 5 tablets in Alu-Alu blister pack.

Manufactured by
SQUARE
PHARMACEUTICALS LTD.
BANGLADESH