Enteca®

Entecavir 0.5mg

COMPOSITION
Each film-coated tablet contains Entecavir 0.5mg.

PHARMACOLOGY
Enteca® is the preparation of Entecavir which is a guanosine nucleoside analogue with selective activity against hepatitis B Virus (HBV) polymerase. Entecavir is effectively phosphorylated to the active triphosphate form and competes with the natural substrate deoxyguanosine triphosphate which functionally inhibits reverse transcription actions of HBV polymerase; including base priming, reverse transcription of the negative strand from the pregenomic messenger RNA and synthesis of the positive strand of HBV DNA. Entecavir triphosphate is a weak inhibitor of cellular DNA polymerases and mitochondrial DNA polymerase.

INDICATIONS AND USAGE
Enteca® (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
Enteca® should be administered on an empty stomach (at least 2 hours after a meal and 2 hours before the next meal).

Compensated Liver Disease
Nucleoside-treatment-naïve (≥16 years of age): 0.5 mg once daily.
Lamivudine-refractory or known lamivudine or telbivudine resistance mutations (≥16 years of age): 1 mg once daily.

Decompensated Liver Disease
The 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 given below-

Creatinine Clearance (mL/min)	Usual Dose (0.5 mg)	Lamivudine-Refractory
≥50	0.5mg once daily	1mg once daily
30 to <50	0.25mg once daily OR 0.5mg every 48 hours	0.5mg once daily OR 1mg every 48 hours
10 to <30 0.5mg every 72 hours	0.15mg once daily OR 1mg every 72 hours	0.3mg once daily OR
<10 Hemodialysis* or CAPD (Continuous Ambulatory Peritoneal Dialysis)	0.05mg once daily OR 0.5mg every 7 days	0.1mg once daily OR 1mg every 7 days

*If administered on a hemodialysis day, administer Entecavir after the hemodialysis session.

Hepatic Impairment
No dosage adjustment is necessary for patients with hepatic impairment.

CONTRAINDICATIONS
Entecavir is contraindicated in patients with previously demonstrated hypersensitivity to entecavir or any ingredients other product.

WARNING AND PRECAUTIONS
Severe acute exacerbations of hepatitis B: Severe acute exacerbations of hepatitis B have been reported in patients who have discontinued anti-hepatitis B therapy, including entecavir.

Lactic acidosis and severe hepatomegaly with steatosis: Lactic acidosis and severe hepatomegaly with steatosis, including fatal cases, have been reported with the use of nucleoside analogues, including entecavir, alone or in combination with antiretrovirals. Particular caution should be exercised when administering nucleoside analogues to any patient with known risk factors for liver disease
Lactic acidosis with entecavir use has been reported, often in association with hepatic decompensation, other serious medical conditions, or drug exposures. Patients with decompensated liver disease may be at higher risk for lactic acidosis. Treatment with entecavir should be suspended in any patient who develops clinical or laboratory findings suggestive of lactic acidosis or pronounced hepatotoxicity.

SIDE EFFECTS
The most common side effects of Entecavir are headache, tiredness, dizziness, and nausea. Less common side effects include diarrhea, indigestion, vomiting, sleepiness and trouble sleeping.

USE IN PREGNANCY AND LACTATION
Pregnancy:
Pregnancy Category C
Entecavir should be used during pregnancy only if clearly needed and after careful consideration of the risks and benefits.
Lactation
It is not known whether entecavir is excreted into human milk. Because many drugs are excreted into human milk and because of the potential for serious adverse reactions in nursing infants from entecavir, mothers should be instructed to discontinue 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. Because elderly patients are more likely to have decreased renal function, care should be taken in dose selection, and it may be useful to monitor renal function.

DRUG INTERACTIONS
Since entecavir is primarily eliminated by the kidneys, coadministration of entecavir with drugs that reduce renal function or compete for active tubular secretion may increase serum concentrations of either entecavir or the coadministered drug. Coadministration of entecavir with lamivudine, adefovir dipivoxil, or tenofovir disoproxil fumarate did not result in 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
Enteca® 0.5mg tablet: Each box contains 10 tablets in Alu-Alu blister pack.

Manufactured by
Renata Limited
Dhaka, Bangladesh

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