Enbee 0.5 (Entecavir 0.5 mg) Innerleaf design (English)

Pantone Metallic Coated 8483 c **L - 307 mm X W - 195 mm**

Enbee™
Entecavir

Jenphar Bangladesh | جنفار بنغلاديش

Composition:

Enbee 0.5 Tablet**:** Each film coated tablet contains Entecavir monohydrate INN equivalent to 0.5 mg Entecavir.

Pharmacology:

Enbee is the tradename for Entecavir, a guanosine nucleoside analogue with selective activity against HBV. Entecavir phosphorylated to the active triphosphate (TP) form. By competing with the natural substrate deoxyguanosine TP, Entecavir-TP functionally inhibits the 3 activities of the viral polymerase: (1) priming of the HBV polymerase, (2) reverse transcription of the negative strand DNA from the pregenomic messenger RNA, and (3) synthesis of the positive strand HBV DNA.

Indication:

Enbee (Entecavir) is indicated for the treatment of chronic hepatitis B virus infection in adults and pediatric patients 2 years of age and older.

Dose & administration:

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

Recommended Dosage in Adults:

Compensated Liver Disease: The recommended dose of Enbee for chronic hepatitis B virus infection in nucleoside-inhibitor-treatment-naïve adults and adolescents 16 years of age and older is 0.5 mg once daily.

The recommended dose of Enbee in adults and adolescents (at least 16 years of age) with a history of hepatitis B viremia while receiving Lamivudine or known Lamivudine or telbivudine resistance substitutions is 1 mg once daily.

Decompensated Liver Disease: The recommended dose of Enbee for chronic hepatitis B virus infection in adults with decompensated liver disease is 1 mg once daily.

Recommended Dosage in Pediatric Patients: The recommended dose of Enbee for treatment naïve 2 years of age or older pediatric patients and body weight greater than 30 kg should receive one 0.5 mg tablet once daily.

The recommended dose of Enbee for Lamivudine experienced 2 years of age or older and body weight greater than 30 kg should receive one 1 mg tablet once daily.

Renal Impairment: In adult subjects with renal impairment, the apparent oral clearance of Entecavir decreased as creatinine clearance decrease. 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:

Dosing interval adjustment of Enbee in patients with renal impairment

Creatinine Clearance (mL/min)	50 or greater	30 to less than 50	10 to less than 30	Less than 10, Hemodialysis or CAPD
Usual Dose	0.50 mg every 24 hours	0.50 mg every 48 hours	0.50 mg every 72 hours	0.50 mg every 7 days
Lamivudine-Refractory or Decompensated Liver Disease (1 mg)	1 mg every 24 hours	1 mg every 48 hours	1 mg every 72 hours	1 mg every 7 days

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

Missed Dose: Patients should be advised to take a missed dose as soon as remembered unless it is almost time for the next dose. Patients should not take two doses at the same time.

Contra-indication:

Hypersensitivity to the active substance or to any of the excipients used in this formulation.

Warning and precaution:

Renal impairment: Dosage adjustment is recommended for patients with renal impairment. Therefore, virological response should be closely monitored.

Exacerbations of hepatitis: Acute exacerbation of hepatitis has also been reported in patients who have discontinued hepatitis B therapy. Therefore should be monitored closely during therapy.

Patients with decompensated liver disease: Patients with decompensated liver disease may be at higher risk for lactic acidosis and for specific renal adverse events such as hepatorenal syndrome. Therefore, clinical and laboratory parameters should be closely monitored in this patient population.

Lactic acidosis and severe hepatomegaly with steatosis: Occurrences of lactic acidosis (in the absence of hypoxaemia), sometimes fatal, usually associated with severe hepatomegaly and hepatic steatosis, have been reported with the use of nucleoside analogues. Patients should be followed closely.

Resistance and specific precaution for Lamivudine-refractory patients: Patients with Lamivudine-resistant HBV are at higher risk of developing subsequent Entecavir resistance than patients without Lamivudine resistance. Virological response should be frequently monitored in the Lamivudine-refractory population and appropriate resistance testing should be performed.

Paediatric population: Entecavir should be used in these patients only if the potential benefit justifies the potential risk to the child.

Liver transplant recipients: Renal function should be carefully evaluated before and during Entecavir therapy in liver transplant recipients receiving Cyclosporine or Tacrolimus.

Co-infection with hepatitis C or D: There are no data on the efficacy of Entecavir in patients co-infected with hepatitis C or D virus.

Human immunodeficiency virus (HIV)/HBV co-infected patients not receiving concomitant antiretroviral therapy: Entecavir has not been studied as a treatment for HIV infection and is not recommended for this use.

HIV/HBV co-infected patients receiving concomitant antiretroviral therapy: No data are available on the efficacy of Entecavir in HBeAg-negative patients co-infected with HIV.

General: Patients should be advised that therapy with Entecavir has not been proven to reduce the risk of transmission of HBV and therefore appropriate precautions should still be taken.

Side Effects:

The most common side effects of Entecavir include nausea, headache, dizziness, tiredness. Entecavir can cause serious side effects including lactic acidosis, serious liver problems.

Use in pregnancy & lactation:

Women of childbearing potential: Given that the potential risks to the developing foetus are unknown, women of childbearing potential should use effective contraception.

Pregnancy: There are no adequate data from the use of Entecavir in pregnant women. Entecavir should not be used during pregnancy unless clearly necessary.

Breast-feeding: It is unknown whether Entecavir is excreted in human milk. Breast-feeding should be discontinued during treatment with Entecavir.

Fertility: Toxicology studies in animals administered Entecavir have shown no evidence of impaired fertility.

Drug interaction:

No pharmacokinetic interactions between Entecavir and Lamivudine, Adefovir or Tenofovir were observed. Apart from Lamivudine, Adefovir dipivoxil and Tenofovir disoproxil fumarate, the effects of coadministration of Entecavir with medicinal products that are excreted renally or affect renal function have not been evaluated.

Overdose:

There is limited experience of Entecavir overdosage reported in patients.

Storage:

Keep in a cool and dry place below 25° C, protect from light. Keep out of the reach of children.

Packing:

Enbee 0.5 Tablet**:** Each box contains 2X10's tablets in Alu-Alu blister pack.

Manufactured by:
Jenphar Bangladesh Ltd.
Sreepur, Gazipur, Bangladesh.

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