

Replivir®

Entecavir
Tablet

Description

Entecavir is a guanosine nucleoside analogue with activity against HBV polymerase. Entecavir functionally inhibits all activities of the HBV polymerase (reverse transcriptase).

Indications

Entecavir is indicated for the treatment of chronic hepatitis B virus infection in adults and pediatric patients 2 years of age and older with evidence of active viral replication and either evidence of persistent elevation in serum aminotransferases (ALT or AST) 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 is 0.5 mg once daily. For Lamivudine-refractory or known Lamivudine or Telbivudine resistance mutations, the recommended dose of Entecavir is 1 mg once daily. For patients with decompensated liver disease (adult) the recommended dose of Entecavir is 1 mg once daily. Entecavir should be administered on an empty stomach (at least 2 hours after a meal or 2 hours before the next meal).

Dose Adjustment in Renal Impairment

Dose adjustment is recommended for patients with creatinine clearance <50 ml/min, including patients on hemodialysis or continuous ambulatory peritoneal dialysis (CAPD) as shown in below.

Dosing interval adjustment of Replivir® in patients with renal impairment				
Creatinine clearance (ml/min)	≥50	30 to <50	10 to <30	<10 Hemodialysis or CAPD
Recommended dose and dosing interval	0.5 mg every 24 hours	0.5 mg every 48 hours	0.5 mg every 72 hours	0.5 mg every 7 days

Missed Dose

If it is almost time for next dose, skip the missed dose and take the next dose at the proper time. Nobody should take a double dose to make up for the missed dose.

Side Effects

The most common adverse events are headache, fatigue,

dizziness and nausea.

Precautions

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

Contraindications

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

Use in Specific Population

Pregnancy: 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 it is excreted in human milk. Mothers should be instructed not to breast feed if they are taking Entecavir.

Pediatric: Safety and effectiveness of Entecavir in pediatric patients below the age of 2 years have not been established.

Geriatric: 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.

Drug Interactions

Co-administration of Entecavir with Lamivudine or Adefovir dipivoxil did not result in significant drug interactions. The effects of co-administration of Entecavir with other drugs that are eliminated through renal or are known to affect renal function have not been evaluated and patients should be monitored closely for adverse events when coadministered with such drugs.

Overdosage

There is no experience of Entecavir overdosage reported in patients.

Pharmaceutical Precaution

Keep in a dry place and store below 30° C. Protect from light and keep out of the reach of children.

Commercial Pack

Replivir® 0.5 tablet: Box containing 10 tablets in 1x10's Alu-Alu form packs. Each film coated tablet contains Entecavir Monohydrate USP equivalent to Entecavir 0.5 mg.

Replivir® 1 tablet: Box containing 10 tablets in 1x10's Alu-Alu form packs. Each film coated tablet contains Entecavir Monohydrate USP equivalent to Entecavir 1 mg.



Manufactured by

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