

# Caviral

Entecavir

## Composition

**Caviral Tablet:** Each tablet contains Entecavir Monohydrate INN equivalent to Entecavir 0.5 mg.

## Description

Entecavir is a guanosine nucleoside analogue with activity against HBV DNA polymerase. Entecavir functionally inhibits all activities of the HBV DNA 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-naïve adults and adolescents 16 years of age is 0.5 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 Caviral 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      |

## Contraindications:

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

## 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.

## Use in Pregnancy and Lactation

### 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 Use:

Safety and effectiveness of Entecavir in pediatric patients below the age of 2 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.

## Drug Interactions:

Coadministration of Entecavir with Lamivudine or Adefovir dipivoxil did not result in significant drug interactions. The effects of coadministration of Entecavir with other drugs that are renally eliminated or are known to affect renal function have not been evaluated.

## Storage

Store below 30°C & dry place. Keep away from light and out of the reach of children.

## Presentation & Packaging

**Caviral Tablet:** Each commercial box contains 30 tablets in Alu-Alu blister pack.