

## Entecavir INN

**DESCRIPTION**

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

**COMPOSITION**

Each film-coated tablet contains Entecavir INN 0.5 mg.

**INDICATION**

VIR is indicated for the treatment of chronic hepatitis B Virus infection in adults 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 on an empty stomach (at least 2 hours after a meal or 2 hours before the next meal) is 0.5 mg daily.

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 Vir 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

OR AS DIRECTED BY THE PHYSICIAN.

**SIDE EFFECT**

The most common adverse events are headache, fatigue, dizziness and nausea.

**CONTRAINDICATION**

Contraindicated in patients with previously demonstrated 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 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 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.

**DRUG INTERACTION**

Coadministration 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 renally eliminated or are known to affect renal function have not been evaluated.

**OVER DOSE**

There is no experience of Entecavir over dosage reported in patients.

**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.

**SUPPLY**

Each box contains 1×10 tablets in blister strip.

Keep all medicines out of reach of children.  
Store in a cool and dry place, protected from light.

\* Further information is available on request.



Manufactured by:

**The ACME Laboratories Ltd.**  
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07 1231/02