Only for the use of Medical Professionals

Teviral®

Entecavir

Description

Teviral® 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 produces only weak inhibition of normal cellular DNA polymerases and mitochondrial DNA polymerase.

Indication and usage

Teviral® 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

Teviral®

The recommended dose of Teviral® in adults and adolescents (>16 years of age), not previously treated with nucleoside analogues : 0.5 mg once daily.

The recommended dose of Teviral® in adults and adolescents (>16 years of age), receving lamivudine or have known lamivudine resistance : 1 mg once daily.

Teviral® should be taken at least 2 hours before and 2 hours after a meal.

Recommended dosage of Teviral® in patients with renal impairment.

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

* If administered on a hemodialysis day, administer Teviral® after the hemodialysis session. Hepatic Impairment: No dosage adjustment is necessary for patients with hepatic impairment

Use in paediatric patients

Safety and effectiveness of Entecavir in paediatric patients below the age of 16 years have not been established.

Use in pregnancy & lactation

Entecavir should be used during pregnancy only if clearly needed and after careful consideration of the risks and benefits. Mothers should be instructed not to breast-feed if they are taking Entecavir.

Side effects

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

Precautions

Dosage adjustment of Entecavir is recommended for patients with a creatinine clearance <50ml/min including patients on hemodialysis or CAPD. The safety and efficacy of Entecavir in liver transplant recipients are unknown. If Entecavir treatment is determined to be necessary for a liver transplant recipient who has received or is receiving an immunosuppressant that may affect renal function, such as cyclosporine or tacrolimus, renal function must be carefully monitored both before and during treatment with Entecavir.

Contraindications

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

Drug interactions

Teviral®

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.

Warnings

Severe acute exacerbations of hepatitis B have been reported in patients who have discontinued anti-hepatitis B therapy, including Entecavir. Hepatic function should be monitored or at least several months in patients who discontinue anti-hepatitis B therapy.

Pharmaceutical precautions

Store in a cool and dry place. Protect from light.

Presentation

Teviral® 0.5 mg tablet : Each coated tablet contains Entecavir INN 0.5 mg.
Teviral® 1 mg tablet : Each coated tablet contains Entecavir INN 1 mg.

Package quantities

Teviral® 0.5 mg tablet: Carton of 10 tablets in blister pack.
Teviral® 1 mg tablet: Carton of 10 tablets in blister pack.

® Registered Trade Mark

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