

Infovir®

Adefovir Dipivoxil 10 mg.

Presentation

Infovir®: Each tablet contains Adefovir Dipivoxil INN 10 mg.

Description

Adefovir is an acyclic nucleotide analogue of adenosine monophosphate. Adefovir is phosphorylated to the active metabolite, Adefovir diphosphate, by cellular kinases. Adefovir diphosphate inhibits HBV DNA polymerase (reverse transcriptase) by competing with the natural substrate deoxyadenosine triphosphate and by causing DNA chain termination after its incorporation into viral DNA.

Indications and uses

Infovir is indicated for the treatment of chronic hepatitis B in adults & adolescents 12 years of age 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

The recommended dose of Infovir in chronic hepatitis B patients with adequate renal function is 10 mg, once daily, taken orally, without regard to food.

Dose Adjustment in Renal Impairment: Significantly increased drug exposures are seen when Adefovir Dipivoxil is administered to patients with renal impairment. Therefore, the dosing interval of Adefovir Dipivoxil should be adjusted in patients with baseline creatinine clearance < 50 mL/min using the following suggested guidelines-

Dosing interval adjustment of Adefovir Dipivoxil in patients with renal impairment				
	Creatinine clearance (mL/min)			
	≥ 50	20-49	10-19	Haemodialysis patients
Recommended dose and dosing interval	10 mg every 24 hours	10 mg every 48 hours	10 mg every 72 hours	10 mg every 7 days following dialysis

Side-effects

Treatment-related clinical adverse events that occurred in 3% or greater of Adefovir Dipivoxil-treated patients compared with placebo are asthenia, headache, abdominal pain, nausea, flatulence, diarrhea, dyspepsia.

Precautions

Severe acute exacerbation of hepatitis has been reported in patients who have discontinued anti-hepatitis B therapy, including therapy with Adefovir Dipivoxil. Patients who discontinue Adefovir Dipivoxil should be monitored at repeated intervals over a period of time for hepatic function. If appropriate, resumption of anti-hepatitis B therapy may be warranted.

Chronic administration of Adefovir Dipivoxil (10 mg once daily) may result in nephrotoxicity. The overall risk of nephrotoxicity in patients with adequate renal function is low.

However, this is of special importance in patients at risk of or having underlying renal dysfunction and patients taking concomitant nephrotoxic agents such as cyclosporine, tacrolimus, aminoglycosides, vancomycin and non-steroidal anti-inflammatory drugs.

Use in pregnancy and lactation

Pregnancy: There are no adequate and well-controlled studies in pregnant women. Therefore, Adefovir Dipivoxil should be used during pregnancy only if clearly needed and after careful consideration of the risks and benefits.

Lactation: It is not known whether Adefovir is excreted in human milk. Mothers should be instructed not to breast-feed if they are taking Adefovir Dipivoxil.

Pediatric Use

Safety and effectiveness in pediatric patients have not been established.

Geriatric Use

In general, caution should be exercised when prescribing to elderly patients since they have greater frequency of decreased renal or cardiac function due to concomitant disease or other drug therapy.

Drug Interactions

Adefovir does not alter the pharmacokinetics of lamivudine, trimethoprim/sulfamethoxazole, acetaminophen and ibuprofen.

The pharmacokinetics of Adefovir is unchanged when Adefovir Dipivoxil is co-administered with lamivudine, trimethoprim/sulfamethoxazole and acetaminophen. When Adefovir Dipivoxil is co-administered with ibuprofen (800 mg three times daily) increases in Adefovir C_{max} (33%), AUC (23%) and urinary recovery are observed.

Contraindications

Adefovir Dipivoxil is contraindicated in patients with previously demonstrated hypersensitivity to any of the components of the product.

Overdose

If overdose occurs, the patient must be monitored for evidence of toxicity and standard supportive treatment applied as necessary.

Commercial pack

Infovir®: Each box contains 2 blister strips of 10 tablets.

Manufactured by
 **Incepta Pharmaceuticals Ltd**
Savar, Dhaka, Bangladesh
® Registered Trademark

IV2

VN.02