Only for the use of Medical Professionals

Foviral®

Tenofovir Disoproxil Fumarate

Description

Foviral® is a preparation of Tenofovir Disoproxil Fumarate which is a prodrug of Tenofovir. It is an acyclic nucleoside phosphate diester analog of adenosine monophosphate.Tenofovir Disoproxil Fumarate requires initial diester hydrolysis for conversion to Tenofovir and subsequent phosphorylation by cellular enzymes to form Tenofovir diphosphate, an obligate chain terminator. Tenofovir diphosphate inhibits the activity of HIV-1 reverse transcriptase and HBV polymerase by direct binding competition with the natural deoxyribonucleotide substrate and after incorporation into viral DNA, by DNA chain termination.

Indication and usage

Foviral® is indicated for the treatment of:

- Chronic hepatitis B infection with either compensated liver disease (with evidence of viral replications and histologically documented active liver inflammation or fibrosis) or decompensated liver disease.
- HIV infection in combination with other antiretroviral drugs.

Dosage and administration

Adults (over 18 years):

The recommended dose of Tenofovir in chronic Hepatitis B virus or HIV-1 infection in adults is 300 mg once daily taken orally with or without food.

Paediatric patients (≥ 12 years of age and ≥ 35 kg):

For the treatment of HIV-1 in paediatric patients the dose is 300 mg tablet once daily taken orally with or without food.

Elderly

Not recommended over age of 65 years.

Hepatic Impaired Patients

No dose adjustment is required in patients with hepatic impairment.

Renally Impaired Patients

In case of Tenofovir, dosing interval should be adjusted in patients with creatinine clearance <50 ml/min, as detailed below-

Dosage adjustment for patients with altered creatinine clearance

	Creatinine Clearance (ml/min)			Hemodialysis Patients
	≥ 50	30-49	10-29	
Recommended 300 mg dosing interval	Every 24 hours	Every 48 hours	Every 72 to 96 hours	Every 7 days or after a total of approximately 12 hours of dialysis

Use in pregnancy and lactation

No clinical data are available for pregnant women being treated with Tenofovir. Tenofovir should be used during pregnancy only if clearly needed. It is not known whether Tenofovir is excreted in human milk. Therefore it is recommended that mothers being treated with Tenofovir do not breast-feed their infants.

Side effects

Most common side effects are nausea, vomiting, diarrhoea, rash, dizziness, asthenia, hypophosphataemia. Common side effects are fatigue, flatulence, headache, abdominal pain, abdominal distension, increased transaminases. Rare side effects are renal failure, nephrogenic diabetes insipidus, reduced bone density, hypokalaemia, myopathy and rhabdomyolysis.

Contraindications

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

Drug interactions

Tenofovir Disoproxil Fumarate should be avoided with concurrent or recent use of a nephrotoxic medicinal product e.g. aminoglycosides, dipivoxil, cidofovir, foscarnet, ganciclovir, pentamidine, vancomycin, Interleukin-2, amphotericin B. Tenofovir should not be administered with any other medicinal products containing Tenofovir Disoproxil Fumarate. It should not be administered with didanosine, adefovir dipivoxil.

Overdose

There is no experience of Tenofovir overdose reported in patients. If overdose occurs the patient must be monitored for evidence of toxicity & standard supportive treatment applied as necessary.

Precautions

Treatment with Tenofovir should be suspended in any patient who develops acidosis or hepatotoxicity because lactic acidosis and severe hepatomegaly with steatosis, including fatal cases, have been reported with the use of nucleoside analogs, including Tenofovir, in combination with other antiretrovirals. Tenofovir should not be administered concurrently with Emtricitabine & Tenofovir combination or Adefovir Dipivoxil. In case of Exacerbation of hepatitis after discontinuation of treatment, Tenofovir therapy may be associated with severe acute exacerbation of hepatitis. Patients infected with HBV who discontinue Tenofovir should be closely monitored with both clinical and laboratory follow-up for at least several months after stopping treatment.

Pharmaceutical precautions

Store in a cool & dry place. Protect from light. Keep away from the reach of children.

Presentation

Foviral® Tablet**:** Each coated tablet contains Tenofovir Disoproxil Fumarate INN 300 mg.

Package quantities

Foviral® Tablet: Carton of 8 tablets in blister pack.

® Registered Trade Mark

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