Tenoviral®

Tenofovir Disoproxil Fumarate INN

Description
Tenofovir Disoproxil Fumarate an acyclic nucleotide analog of Adenosine Monophosphate, is a prodrug of Tenofovir.

Mode of action
Tenofovir shows activity against HBV polymerase & HIV reverse transcriptase after phosphorylation of the active diphosphate form. Tenofovir diphosphate inhibits viral polymerase by directly competing with the natural substrate deoxyribonucleotide & by causing DNA chain termination after incorporation into viral DNA.

Composition
Tenoviral® 300 mg Tablet: Each film coated tablet contains Tenofovir Disoproxil Fumarate INN 300 mg.

Indications
• Chronic Hepatitis B virus infection in adults
• HIV infected adults with others anti-retroviral

Dosage & administration
The recommended dose of Tenofovir in Chronic Hepatitis B virus infection in adults 12 years of age & other with adequate renal function is 300 mg once daily with or without food.
Dose adjustment in renal impairment: Tenofovir is eliminated by renal excretion, so the exposure of Tenofovir increases in patients with renal dysfunction. Dosing interval should be adjusted in all patients with creatinine clearance <50 ml/min, as detailed below-

Dosing interval adjustment of Tenofovir in patients with renal impairment				
Creatinine Clearance (ml/min)	≥50	30 - 49	10 - 29	In case of Hemodialysis patients
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

Dose adjustment in hepatic impairment: no dose adjustment is required in patients with hepatic impairment.
Pediatric use: Safety & effectiveness of Tenofovir in patients under the age of 12 years have not been established.
Geriatric use: In general, dose selection for the elderly patient should be cautious, keeping in mind the greater frequency of decreased hepatic, renal, or cardiac function.

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

Side effects
The most common side effects are nausea, vomiting, diarrhoea, headache etc.

Use in pregnancy & lactation
Pregnancy: US FDA pregnancy category B. There are no adequate and well-controlled studies in pregnant women. It should be used during pregnancy only if clearly needed.
Lactation: It is not known whether it is excreted in breast milk. Mothers should be instructed not to breast-feed if they are taking Tenofovir.

Precautions
Lactic acidosis/severe hepatomegaly with steatosis: through the risk of occurrence of lactic acidosis is low for Tenofovir, Treatment should be suspended in any patient who develops lactic acidosis or pronounced hepatotoxicity.
Exacerbation of hepatitis after discontinuation of treatment: Discontinuation of anti-HBV therapy may be associated with severe acute exacerbations of hepatitis.
Co-administration with other drugs: Should not be administered concurrently with Emtricitabine, Adefovir or Tenofovir Combination.

Drug interactions
Co-administration of Tenofovir with anti-retroviral, Methadone, Nelfinavir, Oral Contraceptives, or Ribavirin did not result in significant drug interactions.

Over dosage
There is no experience of Tenofovir overdosage reported in patients.
Storage
Store in a cool and dry place, protected from light.

Packaging
Tenoviral® 300 mg Tablet: Each carton contain 6X2 tablets in Alu-Alu blister pack.

Opsonin Pharma
Ideas for healthcare

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Manufactured by
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