Xynovir®

Tenofovir Disoproxil Fumarate Tablet

Presentation
Xynovir® tablet: Each tablet contains Tenofovir Disoproxil Fumarate INN 300 mg.

Description
Tenofovir Disoproxil Fumarate, an acyclic nucleotide analog of adenosine monophosphate, is a prodrug of Tenofovir. It shows activity against HBV polymerase and HIV reverse transcriptase after phosphorylation to the active diphosphate form. Tenofovir diphosphate inhibits viral polymerase (reverse transcriptase) by directly competing with the natural substrate deoxyribonucleotide and by causing DNA chain termination after its incorporation into viral DNA.

Indications and uses
Tenofovir is indicated for the treatment of -

- Chronic hepatitis B virus infection in adults
- HIV-infected adults in combination with other anti-retroviral agents

Dosage and administration
The recommended dose of Tenofovir in chronic hepatitis B virus infection in adults 18 years of age and older 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 to 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 to 49	10 to 29	Haemodialysis patients
Recommended 300 mg dosing interval	Every 24 hours 12 hours of dialysis	Every 48 hours	Every 72 to 96 hours	Every 7 days or after a total of approximately

Dose Adjustment in Hepatic Impairment: No dose adjustment is required in patients with hepatic impairment.

Side effects
The most common side effects are nausea, vomiting, diarrhoea and flatulence.

Precautions
Co-administration with other drugs: Tenofovir should not be administered concurrently with Emtricitabine & Tenofovir combination or Adefovir Dipivoxil.

Lactic Acidosis/Severe Hepatomegaly with Steatosis: Though the risk of occurrence of lactic acidosis is low for Tenofovir, treatment should be suspended in any patient who develops lactic acidosis or hepatotoxicity.

Exacerbation of Hepatitis after Discontinuation of Treatment: Discontinuation of Tenofovir therapy may be associated with severe acute exacerbation of hepatitis.

Use in pregnancy and lactation
Pregnancy: Pregnancy category B. There are, however 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 human milk. Mothers should be instructed not to breast feed if they are taking Tenofovir.

Paediatric Use
Safety and effectiveness of Tenofovir in patients under the age of 12 years have not been established.

Geriatric Use
Clinical studies of Tenofovir did not include sufficient numbers of elderly patients aged 65 years and over to determine whether they respond differently from younger subjects. But care should be taken in dose selection.

Drug Interactions
Co-administration of Tenofovir with anti-retroviral, entecavir, lamivudine, methadone, oral contraceptives, ribavirin and tacrolimus did not result in significant drug interactions. The effects of co-administration of Tenofovir with other drugs that are renally eliminated or are known to affect renal function have not been evaluated.

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

Overdose
There is no experience of Tenofovir overdosage reported in patients.

Commercial pack
Xynovir® tablet: Each box contains 3 blister strips of 4 tablets.

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Dhaka, Bangladesh
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