Proxivir™

Tenofovir Disoproxil Fumarate

Active Ingredient
Tenofovir Disoproxil Fumarate.

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

Dosage & Administration
The recommended dose of Tenofovir in chronic hepatitis B virus infection in adults 18 years of age & 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 t0 29
Haemodialysis patients			
Recommended (300mg) dosing Interval	Every 24 hours		Every 48 hours
Every 72 to 96 hours	Every 7 days or after approximately 12 hours of dialysis		

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

Contraindication & Precaution
Tenofovir is contraindicated in patients with known hypersensitivity to Tenofovir or any component of the product.
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.

Side Effect
The most common side effects are nausea, vomiting, diarrhea & flatulence.

Drug Interaction
Co-administration of Tenofovir with anti-retroviral, Entecavir, Lamivudine, Methadone, oral contraceptives, Ribavirin & 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.

Use in Pregnancy & Lactation
Pregnancy category B. It should be used during pregnancy only if clearly needed. It is not known whether it is excreted in human milk. Mothers should be instructed not to breast feed if they are taking Tenofovir.

Use in Children
Safety & Effectiveness of Tenofovir in pediatric patients below the age of 18 years have not been established.

Preparation
300 mg Tablet.

Manufactured by
SQUARE
PHARMACEUTICALS LTD.
BANGLADESH