Proxivir™

Tenofovir Disoproxil Fumarate

COMPOSITION

Proxivir™ Tablet: Each film coated tablet contains Tenofovir Disoproxil Fumarate INN 300 mg equivalent to 245 mg Tenofovir Disoproxil.

PHARMACOLOGY

Tenofovir Disoproxil Fumarate, an acyclic nucleotide analogue of adenosine monophosphate, is a pro-drug of Tenofovir. It shows activity against hepatitis B virus 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.

INDICATION

Proxivir™ 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	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

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

PRECAUTION

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 & LACTATION

Pregnancy: Pregnancy category B. 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.

PEDIATRIC USE

Safety and effectiveness of Tenofovir in pediatric patients below the age of 18 years have not been established.

GERIATRIC USE

Clinical studies of Tenofovir did not include sufficient numbers of subjects aged 65 years and over to determine whether they respond differently from younger subjects. But care should be taken in dose selection, and it may be useful to monitor renal function.

SIDE EFFECT

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

DRUG INTERACTION

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.

OVERDOSE

There is no experience of Tenofovir overdose reported in patients.

STORAGE

Store in a cool and dry place, protected from light and moisture. Keep the medicine out of the reach of children.

HOW SUPPLIED

Proxivir™ Tablet: Each box contains 12 tablets in Alu-Alu blister pack.

Manufactured by :

SQUARE
PHARMACEUTICALS LTD.
BANGLADESH

TM - Trade Mark

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