T-fovir

Tenofovir Disoproxil Fumarate INN 300mg Tablet

Composition : T-fovir : Each film coated tablet contains Tenofovir Disoproxil Fumarate INN 300mg.

Pharmacology : Tenofovir disoproxil fumarate is an antiviral drug. The oral bioavailability of tenofovir from Tenofovir disoproxil fumarate in fasted subjects is approximately 25%. In vitro binding of tenofovir to human plasma or serum proteins is less than 0.7 and 7.2%, respectively. Following single dose, oral administration of Tenofovir disoproxil fumarate, the terminal elimination half-life of tenofovir is approximately 17 hours. Tenofovir is eliminated by a combination of glomerular filtration and active tubular secretion.

Indications : This tablet is indicated in combination with other antiretroviral agents for the treatment of HIV-1 infection and also indicated for the treatment of chronic hepatitis B.

Dosage and administration : For the treatment of HIV-1 or chronic hepatitis B: The recommended dose of Tenofovir is 300mg once daily taken orally with or without food.

Dosage Adustment for patient with altered Creatinine Clearance :

	Creatinine Clearance (ml/min)			Hemodialysis Patients
	≤ 50	30-49	10-29	
Recommendation 300mg 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. Or, as directed by the registered physician.

Contraindication : This tablet is contraindicated in patients with previously hypersensitivity to any of the components of the product.

Precautions : 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 :** Discontiunation of Tenofovir therapy may be associated with severe acute exacerbation of hepatitis.

Side effects : The most common adverse events that occurred in patients receiving Tenofovir with other antiretroviral agents in mild to moderate GIT events such as nausea, diarrhoea, vomiting and flatulence.

Use in Pregnancy and lactation : Pregnancy category B. There are no adequate and well-controlled studies in pregnant women. Tenofovir should be used during pregnancy only if clearly needed and after careful consideration of the risks and benefits. Because of both the potential for HIV transmission and the potential serious adverse reaction in nursing infants, mother should not be instructed to breast feed if they are receiving Tenofovir.

Use in Child : There is no data available.

Drug Interactions : Didanosin : Tenofovir disoproxil fumarate increases Didanosin concentrations. Use with caution and monitor for evidence of Didanosin toxicity. **Atazanavir:** Co-administration decreases Atazanavir concentrations and increases tenofovir concentration. **Lopinavir/Ritonavir :** Coadministration increases tenofovir concentrations.

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

Storage : Store below 30°C in a dry place.

Packing : T-fovir : Each box contains 7's tablets in blister pack.

Manufactured by
DRUG INTERNATIONAL LTD.
Tongi, Gazipur, Bangladesh

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