Tenbee (Tenofovir disoproxil fumarate) Innerleaf design (English)

Pantone Metallic Coated 8483 C L - 195 mm X W - 255 mm

Tenbee™

Tenofovir Disoproxil Fumarate

Jenphar Bangladesh | جنفار بنغلاديش

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

Pharmacology:
Tenofovir disoproxil fumarate is an acyclic nucleoside phosphonate diester analog of adenosine monophosphate. Tenofovir disoproxil fumarate requires initial diester hydrolysis for conversion to tenofovir and subsequent phosphorylations by cellular enzymes to form tenofovir diphosphate, an obligate chain terminator. Tenofovir diphosphate inhibits the activity of HIV-1 reverse transcriptase and HBV reverse transcriptase by competing with the natural substrate deoxyadenosine 5´- triphosphate and after incorporation into DNA, by DNA chain termination. Tenofovir diphosphate is a weak inhibitor of mammalian DNA polymerases alfa, beta and mitochondrial DNA polymerase gamma.

Indication:
Chronic Hepatitis B
Tenofovir is indicated for the treatment of chronic hepatitis B in adults and pediatric patients 12 years of age and older.
HIV-1 Infection
Tenofovir is indicated in combination with other antiretroviral agents for the treatment of HIV-1 infection in adults and pediatric patients 2 years of age and older.

Dose & Administration:
Recommended dose in adults and pediatric patients 12 years of age and older (35 kg or more)
For the treatment of chronic hepatitis B or HIV-1: The dose is one 300 mg Tenofovir tablet once daily taken orally, without regard to food.
Recommended dose in pediatric patients 2 years to less than 12 years of age
Chronic Hepatitis B
Safety and efficacy of Tenofovir in patients younger than 12 years of age have not been established.
HIV-1 Infection
For the treatment of HIV-1 in pediatric patients 2 years of age and older, the recommended oral dose of tenofovir is 8 mg of tenofovir disoproxil fumarate per kilogram of body weight (up to a maximum of 300 mg) once daily administered as oral powder or tablets.
Table 01: Dosing Recommendations for Pediatric Patients ≥2 Years of Age and Weighing ≥17 kg Using Tenofovir Tablets

Body Weight (kg)	Tablets Once Daily
17 to <22	150 mg
22 to <28	200 mg
28 to <35	250 mg
35	300 mg

Dose Adjustment for Renal Impairment in Adults
Significantly increased drug exposures occurred when Tenofovir was administered to subjects with moderate to severe renal impairment. Therefore, the dosing interval of Tenofovir tablets 300 mg should be adjusted in patients with renal impairment using the recommendations in table 02.
Table 02: Dosage adjustment for patients with altered creatinine clearance

	Creatinine Clearance (ml/min)			Hemodialysis Patients
	50	30–49	10–29	
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

Special populations
Gender: Tenofovir pharmacokinetics are similar in male and female subjects.
Geriatric population: Pharmacokinetic trials have not been performed in the elderly (65 years and older).
Pediatric Patients 2 Years of Age and Older: Steady-state pharmacokinetics of tenofovir were evaluated in 31 HIV-1 infected pediatric subjects 2 to less than 18 years
Renal impairment: Dose adjustment is required in case of renal impairment
Hepatic impairment: No change in Tenbee dosing is required in patients with hepatic impairment.

Contra-indication:
None

Warning & Precaution:
Lactic Acidosis/Severe Hepatomegaly with Steatosis
Lactic acidosis and severe hepatomegaly with steatosis, including fatal cases, have been reported with the use of nucleoside analogs, including Tenofovir, in combination with other antiretrovirals.
Discontinuation of anti-HBV therapy, including Tenofovir, may be associated with severe acute exacerbations of hepatitis. Patients infected with HBV who discontinue Tenofovir should be closely monitored with both clinical and laboratory follow-up for at least several months after stopping treatment
New Onset or Worsening Renal Impairment
Tenofovir is principally eliminated by the kidney. Renal impairment, including cases of acute renal failure and Fanconi syndrome (renal tubular injury with severe hypophosphatemia), has been reported with the use of Tenofovir.
Coadministration with Other Products
Tenofovir should not be administered in combination with Adefovir dipivoxil
Patients Coinfected with HIV-1 and HBV
Due to the risk of development of HIV-1 resistance, Tenofovir should only be used in HIV-1 and HBV coinfected patients as part of an appropriate antiretroviral combination regimen.
Bone Effects
In clinical trials in HIV-1 infected adults, Tenofovir was associated with slightly greater decreases in bone mineral density (BMD)
Fat Redistribution
In HIV-infected patients redistribution/accumulation of body fat including central obesity, dorsocervical fat enlargement (buffalo hump), peripheral wasting, facial wasting, breast enlargement, and "cushingoid appearance" have been observed in patients receiving combination antiretroviral therapy.
Immune Reconstitution Syndrome
Immune reconstitution syndrome has been reported in HIV-infected patients treated with combination antiretroviral therapy, including Tenofovir.
Early Virologic Failure
In particular, early virological failure and high rates of resistance substitutions have been reported. Triple nucleoside regimens should therefore be used with caution.

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

Use in Pregnancy and Laction:
Pregnancy
Pregnancy category of Tenofovir is B. Tenofovir should be used during pregnancy only if clearly needed.
Lactation
Mothers should be instructed not to breast-feed if they are receiving Tenofovir.

Drug Interactions:
Didanosine
Coadministration of Tenofovir and Didanosine should be undertaken with caution and patients receiving this combination should be monitored closely because when administered with Tenofovir, Cmax and AUC of Didanosine increased significantly.
HIV-1 Protease Inhibitors
Tenofovir decreases the AUC and Cmin of Atazanavir. When coadministered with Tenofovir, it is recommended that Atazanavir 300 mg is given with ritonavir 100 mg. Tenofovir should not be coadministered with Atazanavir without Ritonavir.
Drugs Affecting Renal Function
Since Tenofovir is primarily eliminated by the kidneys, coadministration of Tenofovir with drugs that reduce renal function or compete for active tubular secretion may increase serum concentrations of Tenofovir and/or increase the concentrations of other renally eliminated drugs.

Overdose:
If overdose occurs the patient must be monitored for evidence of toxicity, and standard supportive treatment applied as necessary.

Storage:
Keep in a cool and dry place below 25° C, protect from light. Keep out of the reach of children.

Packing:
Tenbee Tablet: Each box contains 2×6's tablets in Alu-Alu blister pack.

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Manufactured by:
Jenphar Bangladesh Ltd.
Sreepur, Gazipur, Bangladesh.