Telabee (Tenofovir Alafenamide) Innerleaf design (English) Revise

Pantone 185C & Metallic Coated 8483 C

L - 195 mm X W - 255 mm

Telabee™

Tenofovir Alafenamide

Jenphar Bangladesh | جنفار بنغلاديش

Composition:
Telabee 25 Tablet: Each film-coated tablet contains Tenofovir Alafenamide Fumarate INN equivalent to Tenofovir Alafenamide 25 mg.

Pharmacology:
Tenofovir Alafenamide INN is a phosphonamidate prodrug of Tenofovir (2'-deoxyadenosine monophosphate analogue). Tenofovir Alafenamide INN enters primary hepatocytes by passive diffusion and by the hepatic uptake transporters OATP1B1 and OATP1B3. Tenofovir Alafenamide is primarily hydrolyzed to form Tenofovir by carboxylesterase 1 in primary hepatocytes. Intracellular Tenofovir is subsequently phosphorylated to the pharmacologically active metabolite Tenofovir diphosphate. Tenofovir diphosphate inhibits HBV replication through incorporation into viral DNA by the HBV reverse transcriptase, which results in DNA chain termination.

Indication:
Tenofovir Alafenamide is indicated for the treatment of chronic hepatitis B virus (HBV) infection in adults with compensated liver disease.

Dose & administration:
Recommended dosage: 25 mg (one tablet) taken orally once daily with food.
Dose Adjustment for Renal Impairment:
No dosage adjustment of Tenofovir Alafenamide is required in patients with mild, moderate, or severe renal impairment. Tenofovir Alafenamide is not recommended in patients with estimated creatinine clearance below 15 ml per minute.
Dose Adjustment for Hepatic Impairment:
No dosage adjustment of Tenofovir Alafenamide is required in patients with mild hepatic impairment (Child-Pugh A). Tenofovir Alafenamide is not recommended in patients with decompensated (Child-Pugh B or C) hepatic impairment.

Contra-indication:
None

Warning and precaution:
Severe Acute Exacerbation of Hepatitis B after Discontinuation of Treatment:
Discontinuation of anti-hepatitis B therapy, including Tenofovir Alafenamide, may result in severe acute exacerbations of hepatitis B. Patients who discontinue Tenofovir Alafenamide should be closely monitored with both clinical and laboratory follow-up for at least several months after stopping treatment. If appropriate, resumption of anti-hepatitis B therapy may be warranted.
Risk of Development of HIV-1 Resistance in Patients Coinfected with HBV & HIV-1:
Due to the risk of development of HIV-1 resistance, Tenofovir Alafenamide alone is not recommended for the treatment of HIV-1 infection. The safety and efficacy of Tenofovir Alafenamide have not been established in patients coinfected with HBV and HIV-1. HIV antibody testing should be offered to all HBV-infected patients before initiating therapy with Tenofovir Alafenamide, and, if positive, an appropriate antiretroviral combination regimen that is recommended for patients coinfected with HIV-1 should be used.
New Onset or Worsening Renal Impairment:
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 prodrugs in both animal toxicology studies and human trials. In clinical trials of Tenofovir Alafenamide, there have been no cases of Fanconi syndrome or Proximal Renal Tubulopathy (PRT).
Patients taking tenofovir prodrugs who have impaired renal function and those taking nephrotoxic agents, including non-steroidal anti-inflammatory drugs, are at increased risk of developing renal-related adverse reactions.
It is recommended that serum creatinine, serum phosphorous, estimated creatinine clearance, urine glucose, and urine protein be assessed before initiating Tenofovir Alafenamide and during therapy in all patients as clinically appropriate. Discontinue Tenofovir Alafenamide in patients who develop clinically significant decreases in renal function or evidence of Fanconi syndrome.
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 DF, another prodrug of tenofovir, alone or in combination with other antiretrovirals. Treatment with Tenofovir Alafenamide should be suspended in any patient who develops clinical or laboratory findings suggestive of lactic acidosis or pronounced hepatotoxicity (which may include hepatomegaly and steatosis even in the absence of marked transaminase elevations).

Side effects:
Most common adverse reactions (incidence greater than or equal to 5%, all grades) are headache, abdominal pain, fatigue, cough, nausea, and back pain.

Use in specific population:
Pregnancy & laction:
Pregnancy: There are no human data on the use of Tenofovir Alafenamide in pregnant women to inform a drug-associated risks of adverse fatal developmental outcome. In animal studies, no adverse developmental effects were observed when Tenofovir Alafenamide was administered during the period of organogenesis at exposure equal to or 51 times (rats and rabbits, respectively) the Tenofovir Alafenamide exposure at the recommended daily dose of Tenofovir Alafenamide. No adverse effects were observed in the offspring when TDF (tenofovir disoproxil fumarate) was administered through lactation at tenofovir exposures of approximately 12 times the exposure at the recommended daily dosage of Tenofovir Alafenamide.
Lactation: It is not known whether Tenofovir Alafenamide is secreted in human milk. However, in animal studies it has been shown that Tenofovir is secreted into milk. There is insufficient information on the effects of Tenofovir in newborns/infants. A risk to the breastfed child cannot be excluded; therefore, Tenofovir Alafenamide should not be used during breast-feeding.

Drug interaction:
Potential for Other Drugs to Affect Tenofovir Alafenamide:
Tenofovir Alafenamide is a substrate of P-glycoprotein (P-gp) and BCRP. Drugs that strongly affect P-gp and BCRP activity may lead to changes in Tenofovir Alafenamide absorption (see Table 4). Drugs that induce P-gp activity are expected to decrease the absorption of Tenofovir Alafenamide, resulting in decreased plasma concentrations of Tenofovir Alafenamide, which may lead to loss of therapeutic effect of Tenofovir Alafenamide. Coadministration of Tenofovir Alafenamide with other drugs that inhibit P-gp and BCRP may increase the absorption and plasma concentration of Tenofovir Alafenamide.
Drugs Affecting Renal Function:
Because tenofovir is primarily excreted by the kidneys by a combination of glomerular filtration and active tubular secretion, coadministration of Tenofovir Alafenamide with drugs that reduce renal function or compete for active tubular secretion may increase concentrations of tenofovir and other renally eliminated drugs and this may increase the risk of adverse reactions. Some examples of drugs that are eliminated by active tubular secretion include, but are not limited to, acyclovir, cidofovir, ganciclovir, valacyclovir, valganciclovir, aminoglycosides (e.g., gentamicin), and high-dose or multiple NSAIDs.
Established and Other Potentially Significant Interactions:
below table provides a listing of established or potentially clinically significant drug interactions. The drug interactions described are based on studies conducted with Tenofovir Alafenamide or are predicted drug interactions that may occur with Tenofovir Alafenamide.
Established and Other Potentially Significant Drug Interactions[a]:

Concomitant Drug Class: Drug Name	***Effect on Concentration[b]***	***Clinical Comment[b]***
Anticonvulsants: carbamazepine[c]* oxcarbazepine* phenobarbital* phenytoin*	↓Tenofovir Alafenamide	When coadministered with carbamazepine, the Tenofovir Alafenamidedose should be increased to two tablets once daily. Coadministration of Tenofovir Alafenamidewith oxcarbazepine, phenobarbital or phenytoin is not recommended.
Antimycobacterial: Rifabutin* Rifampin* Rifapentine*	↓Tenofovir Alafenamide	Coadministration of Tenofovir Alafenamidewith rifabutin, rifampin or rifapentine is not recommended.
Herbal Products: St. John's wort* (Hypericum perforatum)	↓Tenofovir Alafenamide	Coadministration of Tenofovir Alafenamidewith St. John's wort is not recommended.

a. This table is not all inclusive b. ↓ = decrease c. Indicates that a drug interaction study was conducted * P-gp inducer

Drugs without Clinically Significant Interactions with Tenofovir Alafenamide:
Based on drug interaction studies conducted with Tenofovir Alafenamide, no clinically significant drug interactions have been observed with: ethinyl estradiol, itraconazole, ketoconazole, ledipasvir/sofosbuvir, midazolam, norgestimate, sertraline, and sofosbuvir.

Overdose:
If overdose occurs, monitor patient for evidence of toxicity. Treatment of overdosage with Tenofovir Alafenamide consists of general supportive measures including monitoring of vital signs as well as observation of the clinical status of the patient. Tenofovir is efficiently removed by hemodialysis with an extraction coefficient of approximately 54%.

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

Packing:
Telabee 25 Tablet: Each box contains 1×10's film coated tablets in Alu-Alu blister pack.

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

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