Alenvir™

Tenofovir Alafenamide

Composition

Alenvir™ : Each tablet contains Tenofovir Alafenamide Fumarate INN equivalent

Description Tenofovir Alafenamide, a hepatitis B virus (HBV) nucleoside analog reverse transcriptase inhibitor, is converted into tenofovir, an acyclic nucleoside phosphonate (nucleotide) analog of adenosine 5 -monophosphate.

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

Dosage & Administration

The recommended dosage of Tenofovir Alafenamide is 25 mg (one tablet) taken orally once daily with food. No dosage adjustment is required in patients with mild, moderate, or severe renal impairment. Tenofovir Alafenamide is not recommended in patients with end stage renal disease (estimated creatinine clearance below 15 mL/min). No dosage adjustment 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.

Side Effects

Lactic acidosis and severe hepatomegaly with steatosis, including fatal cases, have been reported with the use of nucleoside analogs, including tenofovir disoproxil fumarate in combination with other antiretrovirals. A majority of these cases have been in women.

Precautions Tenofovir Alafenamide alone should not be used in patients with HIV infection. Lactic acidosis and severe hepatomegaly with steatosis have been reported with the use of nucleoside analogs. 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.

Use in Pregnancy & Lactation It is not known whether Tenofovir Alafenamide and its metabolites are present in human breast milk, affect human milk production, or have effects on the breastfed infant. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for Tenofovir Alafenamide and any potential adverse effects on the breastfed infant.

Drug Interaction

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. 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, sofosbuvir, and sofosbuvir/velpatasvir.

Over Dose

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.

Storage

Store in cool and dry place (below 30o c) and protect from light and moisture. Keep out of the reach of children.

How Supplied

Alenvir™ : Each box contains 1 blister strip of 10 tablets.

Manufactured by

SQUARE

PHARMACEUTICALS LTD.

BANGLADESH