T-Fovir A
Tablet

DRUG INTERNATIONAL LTD.

Composition : Each film coated tablet contains Tenofovir Alafenamide 25mg as Tenofovir Alafenamide Fumarate INN.

Pharmacology : 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 : It is indicated for the treatment of chronic hepatitis B virus infection in adults with compensated liver disease.

Dosage and administration : The recommended dosage is 25 mg (one tablet) taken orally once daily with food. Or, as directed by the registered physician.

No dosage adjustment of T-Fovir A is required in patients with mild, moderate, or severe renal impairment. It 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). It is not recommended in patients with decompensated (Child-Pugh B or C) hepatic impairment.

Contraindication : It is contraindicated in patients with known hypersensitivity to Tenofovir Alafenamide or to any of the components of this product.

Precaution : 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 Tenofivir Alafenamide, may result in severe acute exacerbations of hepatitis B. Patients who discontinue Tenofivir Alafenamide should be closely monitored with both clinical and laboratory follow-up for at least several months after stopping treatment.

Side effects : Most common adverse reaction is headache. Lactic acidosis and severe hepatomegaly with steatosis, including fatal cases, have been reported with the use of nucleoside analogs, including Tenofovir Disoproxil Fumarate, alone or in combination with other antiretrovirals. A majority of these cases have been in women.

Use in pregnancy and lactation : There are no human data on the use of Tenofovir Alafenamide in pregnant women to inform a drug-associated risk of adverse fetal developmental outcome. 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.

Use in child : Safety and effectiveness of T-Fovir A in pediatric patients less than 18years of age have not been established.

Drug interactions : 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.

Overdose : If overdose occurs, monitor patient for evidence of toxicity. Treatment of overdosage with T-Fovir A consists of general supportive measures including monitoring of vital signs as well as observation of the clinical status of the patient.

Storage : Store below 30°C in a cool and dry place. Protect form light and moisture. Keep out of the reach of children.

Packing : Each box contains 10's tablets in blister pack.