

TENOCRUZ AF

For the use of a Registered Medical Practitioner or Hospital or a Laboratory only.

Abbreviated Prescribing information for TENOCRUZ AF (Tenofovir Alafenamide
Tablets 25mg)

[Please refer the complete prescribing information available at www.torrentpharma.com]

PHARMACOLOGICAL PROPERTIES:

Mechanism of action: Tenofovir alafenamide is a phosphoramidate prodrug of tenofovir (2'-deoxyadenosine monophosphate analogue). Tenofovir alafenamide enters primary hepatocytes by passive diffusion and by the hepatic uptake transporters OATP1B1 and OATP1B3. Tenofovir alafenamide is primarily hydrolysed 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.

DOSAGE AND ADMINISTRATION: One tablet once daily or as directed by Gastroenterologist/ Hepatologist.

CONTRAINDICATION:

Hypersensitivity to the active substance or to any of the excipients.

WARNINGS & PRECAUTIONS: HBV transmission, Patients with decompensated liver disease, Exacerbation of hepatitis, Renal impairment, Nephrotoxicity, Patients co-infected with HBV and hepatitis C or D virus, Hepatitis B and HIV co-infection, Co-administration with other medicinal products, Lactose intolerance, Excipients.

ADVERSE REACTIONS: Headache, Dizziness, Diarrhoea, vomiting, nausea, abdominal pain, abdominal distension, flatulence, Increased ALT, Rash, pruritus, Angioedema, urticarial, Arthralgia, Fatigue.

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IN/ TENOCRUZ AF 25 mg/SEP-20/01/ABPI

(Additional information is available on request)