

TENOCRUZ

For the use of a Registered Medical Practitioner or a Hospital or a Laboratory Only

Abbreviated Prescribing information for **Tenocruz** [Tenofovir Disoproxil Fumarate I.P. 300 mg]
[Please refer the complete prescribing information available at www.torrentpharma.com]

PHARMACOLOGICAL PROPERTIES:

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.

INDICATION: Tenocruz is indicated as Anti-HIV and for treatment of chronic Hepatitis B in adults.

DOSAGE AND ADMINISTRATION: Tenocruz is indicated as Anti-HIV and for treatment of chronic Hepatitis B in adults.

CONTRAINDICATION: None

WARNINGS & PRECAUTIONS: 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.

Severe acute exacerbations of hepatitis have been reported in HBV-infected patients who have discontinued anti-hepatitis B therapy, including Tenofovir. Hepatic function should be monitored closely with both clinical and laboratory follow-up for at least several months in patients who discontinue anti-hepatitis B therapy, including Tenofovir. If appropriate, resumption of anti-hepatitis B therapy may be warranted.

DRUG INTERACTIONS: Didanosine, Atazanavir, Lopinavir/ritonavir, 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. Some examples include, but are not limited to, didanosine, acyclovir, valacyclovir, ganciclovir, and valganciclovir.

ADVERSE REACTIONS: Rash, diarrhea, headache, pain, depression, asthenia, dizziness, fever, abdominal pain, chest pain, nausea, dyspepsia, anorexia, flatulence, vomiting, pneumonia, depression, insomnia, peripheral neuropathy, anxiety, pruritus, maculopapular rash, urticaria, vesiculobullous rash, and ustular rash, sweating, myalgia, weight loss, allergic reaction, including angioedema, lactic acidosis, hypokalemia, hypophosphatemia, dyspnea, pancreatitis, increased amylase, hepatic steatosis, hepatitis, increased liver enzymes (most commonly AST, ALT gamma GT), rhabdomyolysis, osteomalacia (manifested as bone pain and which may contribute to fractures), muscular weakness, myopathy, acute renal failure, acute tubular necrosis, fanconi syndrome, proximal renal tubulopathy, interstitial nephritis (including acute cases) nephrogenic diabetes insipidus, renal insufficiency, increased creatinine, proteinuria and polyuria.

MARKETED BY:



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(Additional information is available on request)