Calculated using ideal (lean) body weight.

CrCl 10 to 29 mL/min: 300 mg every 72 to 96 hours. [2.4]

...non-steroidal anti-inflammatory drugs (NSAIDs))
high-dose or multiple NSAIDs have been reported in HIV-infected patients with risk factors for renal dysfunction who appeared stable on TDF. Some

Clinical trials evaluating tenofovir disoproxil fumarate in pediatric subjects were conducted. Under normal circumstances, BMD increases

Immune reconstitution syndrome has been reported in HIV-1 infected patients treated with combination antiretroviral therapy, including tenofovir

300 mg Tablets: 300 mg of TDF (equivalent to 245 mg of tenofovir disoproxil): white to off-white, oval shaped, biconvex, film-coated tablets

•

250 mg Tablets: 250 mg of TDF (equivalent to 204 mg of tenofovir disoproxil): white to off-white, capsule shaped, biconvex, film-coated tablets

Table 1

Tablets: 150 mg, 200 mg, 250 mg, and 300 mg of tenofovir disoproxil fumarate. [3]

Tenofovir disoproxil fumarate tablets are indicated in combination with other antiretroviral agents for the treatment of human immunodeficiency virus

1

immune reconstitution; however, the time to onset is more variable, and can occur many months after initiation of treatment.

Autoimmune disorders (such as Graves' disease, polymyositis, and Guillain-Barré syndrome) have also been reported to occur in the setting of

Severe Acute Exacerbation of Hepatitis B in Patients with HBV Infection

Table 4

Frequencies of adverse reactions are based on all treatment-emergent adverse events, regardless of relationship to study drug.

Severe acute exacerbations of hepatitis B virus (HBV) have been reported in HBV-infected patients who have discontinued anti-hepatitis B

Recommended T ablet Dosage in Adults and Pediatric Patients 2 Years and Older Weighing at Least 17 kg

Body Weight (kg) Dosing of Tenofovir Disoproxil Fumarate Tablets

8

Table 5

Over view of Clinical Trials

Cumulative incidence of

≥

Tenofovir Disoproxil

≥

Tenofovir Disoproxil

1% of Tenofovir Disoproxil Fumarate-Treated Subjects in Trial 903 (0

Revise: 06/2019

Tenofovir disoproxil fumarate should be administered following completion of dialysis.

Recommended Every 24 hours Every 48 hours Every 72 to 96 hours

DOSAGE AND ADMINISTRATION

1.2

DRUG INTERACTIONS

Peripheral neuropathy includes peripheral neuritis and neuropathy.

Fumarate

Over view of Clinical Trials

Depression 4% 3% 8% 4%

Data

Clinical trials of tenofovir disoproxil fumarate in adults.

Abdominal pain 4% 3% 7% 6%

Table 6

Data

Lipid metabolism

Trial 115

Diabetes 3% 3% 5% 3%

Table 7

Lipid metabolism

Rash eventc 5% 4% 7% 1%

Table 8

Lipid metabolism

Creatine Kinase ≥150 U/L 3% 3% 5% 3%

Table 9

Lipid metabolism

Lipid metabolism

Lipid metabolism

Lipid metabolism

Lipid metabolism

Lipid metabolism

Lipid metabolism
Tenofvir disoproxil fumarate to pre-existing AZT resistance-associated substitutions (M41L, D67N, K70R, L210W, T215Y/F, or K219Q/E/N) were observed and appeared. Several exploratory analyses were conducted to evaluate the effect of specific substitutions and substitutional patterns on virologic outcome. Because experienced subjects participating in Trials 902 and 907. In these clinical trials, 94% of the participants evaluated had baseline HIV-1 isolates of the K65R substitution in the HIV-1 RT gene. 14/304 (5%) of the tenofvir disoproxil fumarate-treated subjects with virologic failure through Week [see Clinical Studies (14.2)] detected K65R substitution in their HIV-1 as analyzed through standard genotypic analysis. Microbiology,