

TENOFOVIR (TDF) (Updated August 2011)									
Trade Name	Viread								
Classification	Nucleotide Reverse Transcriptase Inhibitor								
Form	300-mg tablets Each Truvada tablet contains TDF 300 mg and FTC 200 mg Each Atripla tablet contains EFV 600 mg, FTC 200 mg, and TDF 300 mg Each Complera tablet contains FTC 200 mg, RPV 25 mg, and TDF 300 mg								
Dosing Recommendations	300 mg once daily <i>or</i> with FTC as Truvada, 1 once daily <i>or</i> with EFV and FTC as Atripla, 1 once daily								
Renal Impairment Dosing	<table border="1"> <thead> <tr> <th>CrCl (mL/min)</th> <th>Dose</th> </tr> </thead> <tbody> <tr> <td>30-49</td> <td>300 mg q48h</td> </tr> <tr> <td>10-29</td> <td>300 mg bi wk</td> </tr> <tr> <td>ESRD</td> <td>300 mg q wk</td> </tr> </tbody> </table>	CrCl (mL/min)	Dose	30-49	300 mg q48h	10-29	300 mg bi wk	ESRD	300 mg q wk
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Food Effect	Fatty meal ↑ TDF AUC 40% Co-administration of TDF + ddI buffered tablets should be on an empty stomach TDF + ddI EC may be taken on an empty stomach or with a light meal								
Oral Bioavailability	25% in fasting state; 39% with high-fat meal								
Serum Half-life	17 hours								
Intracellular Half-life	10-50 hours								
Elimination	Renal excretion								
Adverse Events	Asthenia, headache, diarrhea, nausea, vomiting, flatulence Although there have been no cases of lactic acidosis reported with TDF use, lactic acidosis with hepatic steatosis is a rare but potentially life-threatening toxicity with the use of NRTIs Rare reports of renal insufficiency								
FDA Pregnancy Category	B (one study showed normal growth; however, there was a decrease in fetal bone porosity and insulin-like growth factor was observed)								
Long-Term Animal Carcinogenicity Studies	Negative (rats); in female mice, liver adenomas were increased at exposures 16 times that in humans								
Animal Teratogen Studies	Negative (osteomalacia when given to juvenile animals at high doses)								
Black Box Warnings	Lactic acidosis and severe hepatomegaly with steatosis, including fatal cases, have been reported with the use of nucleoside analogs alone or in combination with other antiretrovirals. Viread has <i>in vitro</i> activity against HBV but is not indicated for the treatment of chronic hepatitis B virus (HBV) infection and the safety and efficacy of Viread have not been established in patients co-infected with HBV and HIV. Severe acute								

	exacerbations of hepatitis B have been reported in patients who are co-infected with HBV and HIV and have discontinued Viread. Hepatic function should be monitored closely with both clinical and laboratory follow-up for at least several months in patients who discontinue Viread and are co-infected with HIV and HBV. If appropriate, initiation of anti-hepatitis B therapy may be warranted.
Drugs to Avoid	As part of the ARV regimen: Atazanavir without ritonavir Didanosine + delavirdine Didanosine + efavirenz Didanosine + nevirapine Lamivudine + abacavir Lamivudine + didanosine
Cautious Use or Dose Adjustment	
Antiretrovirals	Atazanavir + ritonavir: ATV AUC ↓ 25%, Cmin ↓ 23% – Use ATV 300 mg + RTV 100 mg once daily Didanosine: ddI AUC ↑ 44%, Cmax ↑ 28% – Monitor for ddI-associated toxicities; for patients ≥60 kg, ↓ ddI EC dose to 250 mg once daily; for patients <60 kg ↓ ddI EC to 200 mg once daily. Avoid combination in patients with renal failure
Antivirals	Cidofovir, ganciclovir, valganciclovir: May ↑ serum concentration of these drugs and/or TDF – Monitor for dose-related toxicities
Uricosuric Agents	Trimethoprim, probenecid: May ↑ serum concentration of these drugs and/or TDF – Monitor for dose-related toxicities