

FULL PRESCRIBING INFORMATION

WARNING: POSTTREATMENT ACUTE EXACERBATION OF HEPATITIS B

Severe acute exacerbations of hepatitis B virus (HBV) have been reported in HBV-infected patients who have discontinued anti-hepatitis B therapy, including VIREAD. Hepatic function should be monitored closely with both clinical and laboratory follow-up for at least several months in HBV-infected patients who discontinue anti-hepatitis B therapy, including VIREAD. If appropriate, resumption of anti-hepatitis B therapy may be warranted [see *Warnings and Precautions (5.1)*].

1 INDICATIONS AND USAGE

1.1 HIV-1 Infection

VIREAD is indicated in combination with other antiretroviral agents for the treatment of human immunodeficiency virus type 1 (HIV-1) infection in adults and pediatric patients 2 years of age and older weighing at least 10 kg.

1.2 Chronic Hepatitis B

VIREAD is indicated for the treatment of chronic hepatitis B virus (HBV) in adults and pediatric patients 2 years of age and older weighing at least 10 kg.

2 DOSAGE AND ADMINISTRATION

2.1 Testing Prior to Initiation of VIREAD for Treatment of HIV-1 Infection or Chronic Hepatitis B

Prior to or when initiating VIREAD, test patients for HBV infection and HIV-1 infection. VIREAD alone should not be used in patients with HIV-1 infection [see *Warnings and Precautions (5.3)*].

Prior to initiation and during use of VIREAD, on a clinically appropriate schedule, assess serum creatinine, estimated creatinine clearance, urine glucose and urine protein in all patients. In patients with chronic kidney disease, also assess serum phosphorus [see *Warnings and Precautions (5.2)*].

2.2 Recommended Tablet Dosage in Adults and Pediatric Patients 2 Years and Older Weighing at Least 17 kg

The recommended dosage of VIREAD in adults and pediatric patients weighing at least 35 kg is one 300 mg tablet taken orally once daily **without regard to food**. The dosage for VIREAD is the same for both HIV and HBV indications.

The recommended dosage of VIREAD tablet in adults and pediatric patients 2 years and older weighing at least 17 kg is 8 mg of tenofovir disoproxil fumarate (TDF) per kg of body weight (up to a maximum of 300 mg) once daily. Dosage for pediatric patients 2 years and older weighing between 17 kg and 35 kg and able to swallow an intact tablet is provided in Table 1. Weight should be monitored periodically and the VIREAD dose adjusted accordingly.