

HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use EMTRICITABINE AND TENOFIDROXIL FUMARATE TABLETS safely and effectively. See full prescribing information for EMTRICITABINE AND TENOFIDROXIL FUMARATE TABLETS.

EMTRICITABINE AND TENOFIDROXIL FUMARATE TABLETS, for oral use
Initial U.S. Approval: 2004

WARNING: POSTTREATMENT ACUTE EXACERBATION OF HEPATITIS B AND RISK OF DRUG RESISTANCE WITH USE OF EMTRICITABINE AND TENOFIDROXIL FUMARATE TABLETS FOR HIV-1 PRE-EXPOSURE PROPHYLAXIS (PrEP) IN UNDIAGNOSED EARLY HIV-1 INFECTION

See full prescribing information for complete boxed warning.

- Severe acute exacerbations of hepatitis B (HBV) have been reported in HIV-infected individuals who have discontinued emtricitabine and tenofovir disoproxil fumarate. Hepatic function should be monitored closely in these individuals who discontinue emtricitabine and tenofovir disoproxil fumarate. If appropriate, anti-hepatitis B therapy may be warranted. (5.1)

- Emtricitabine and tenofovir disoproxil fumarate used for HIV-1 PrEP must only be prescribed to individuals confirmed to be HIV-negative immediately prior to initiating and at least every 3 months during use. Drug-resistant HIV-1 variants have been identified with the use of emtricitabine and tenofovir disoproxil fumarate for HIV-1 PrEP following undetected acute HIV-1 infection. Do not initiate emtricitabine and tenofovir disoproxil fumarate for HIV-1 PrEP if signs or symptoms of acute HIV infection are present unless negative status is confirmed. (5.2)

INDICATIONS AND USAGE

HIV-1 Treatment (1.1)
Emtricitabine and tenofovir disoproxil fumarate tablets are a two-drug combination of emtricitabine (FTC) and tenofovir disoproxil fumarate (TDF), both HIV-1 nucleoside analog reverse transcriptase inhibitors, and is indicated:

- in combination with other antiretroviral agents for the treatment of HIV-1 infection in adults and pediatric patients weighing at least 17 kg.

HIV-1 PrEP (1.2)
Emtricitabine and tenofovir disoproxil fumarate tablets are indicated in at-risk adults and adolescents weighing at least 35 kg for pre-exposure prophylaxis (PrEP) to reduce the risk of sexually acquired HIV-1 infection. Individuals must have a negative HIV-1 test immediately prior to initiating emtricitabine and tenofovir disoproxil fumarate tablets for HIV-1 PrEP.

—DOSAGE AND ADMINISTRATION—

- Testing: Prior to or while taking emtricitabine and tenofovir disoproxil fumarate test for hepatitis B virus infection. Prior to initiation and during use of emtricitabine and tenofovir disoproxil fumarate, on a clinically appropriate schedule, assess serum creatinine, estimated creatinine clearance, urine glucose, and urine protein in all individuals. In individuals with chronic kidney disease, also assess serum phosphorus. (2.1)

- HIV-1 Screening: Screen all individuals for HIV-1 infection immediately prior to initiating emtricitabine and tenofovir disoproxil fumarate for HIV-1 PrEP and at least once every 3 months while taking emtricitabine and tenofovir disoproxil fumarate, and upon diagnosis of any other sexually transmitted infections (STIs). (2.2)

Treatment of HIV-1 Infection.

- Recommended dosage in adults and pediatric patients weighing at least 35 kg: One emtricitabine and tenofovir disoproxil fumarate tablet (containing 200 mg of FTC and 300 mg of TDF) once daily taken orally with or without food. (3.3)

- Recommended dosage in pediatric patients weighing at least 17 kg: One emtricitabine and tenofovir disoproxil fumarate low-strength tablet (100 mg/150 mg, 133 mg/200 mg, or 167 mg/250 mg based on body weight) once daily taken orally with or without food. (3.4)

- Recommended dosage in renally impaired HIV-1 infected adult patients:
 - Creatinine clearance (CrCl) 30 to 49 mL/min: 1 tablet every 48 hours. (2.6)
 - CrCl below 30 mL/min or hemodialysis: Emtricitabine and tenofovir disoproxil fumarate tablets are not recommended. (2.6)

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FULL PRESCRIBING INFORMATION

WARNING: POSTTREATMENT ACUTE EXACERBATION OF HEPATITIS B AND RISK OF DRUG RESISTANCE WITH USE OF EMTRICITABINE AND TENOFIDROXIL FUMARATE TABLETS FOR HIV-1 PRE-EXPOSURE PROPHYLAXIS (PrEP) IN UNDIAGNOSED EARLY HIV-1 INFECTION

Severe acute exacerbations of hepatitis B (HBV) have been reported in HIV-infected individuals who have discontinued emtricitabine and tenofovir disoproxil fumarate. Hepatic function should be monitored closely with both clinical and laboratory follow-up for at least several months in individuals who are infected with HBV and discontinue emtricitabine and tenofovir disoproxil fumarate. If appropriate, anti-hepatitis B therapy may be warranted [see Warnings and Precautions (5.1)].

Emtricitabine and tenofovir disoproxil fumarate used for HIV-1 PrEP must only be prescribed to individuals confirmed to be HIV-negative immediately prior to initiating and at least every 3 months during use. Drug-resistant HIV-1 variants have been identified with the use of emtricitabine and tenofovir disoproxil fumarate for HIV-1 PrEP following undetected acute HIV-1 infection. Do not initiate emtricitabine and tenofovir disoproxil fumarate for HIV-1 PrEP if signs or symptoms of acute HIV infection are present unless negative status is confirmed [see Warnings and Precautions (5.2)].

1. INDICATIONS AND USAGE

1.1 Treatment of HIV-1 Infection
Emtricitabine and tenofovir disoproxil fumarate tablets are indicated in combination with other antiretroviral agents for the treatment of HIV-1 infection in adults and pediatric patients weighing at least 17 kg [see Clinical Studies (14)].

1.2 HIV-1 Pre-Exposure Prophylaxis (PrEP)
Emtricitabine and tenofovir disoproxil fumarate tablets are indicated in at-risk adults and adolescents weighing at least 35 kg for pre-exposure prophylaxis (PrEP) to reduce the risk of sexually acquired HIV-1 infection. Individuals must have a negative HIV-1 test immediately prior to initiating emtricitabine and tenofovir disoproxil fumarate for HIV-1 PrEP [see Warnings and Precautions (5.2)].

2. DOSAGE AND ADMINISTRATION

2.1 Testing: Prior to Initiation of Emtricitabine and Tenofovir Disoproxil Fumarate Tablets for Treatment of HIV-1 Infection or for HIV-1 PrEP
Prior to or while taking emtricitabine and tenofovir disoproxil fumarate tablets, test individuals for hepatitis B virus infection [see Warnings and Precautions (5.1)].

2.2 HIV-1 Screening for Individuals Receiving Emtricitabine and Tenofovir Disoproxil Fumarate Tablets for HIV-1 Infection
Screen all individuals for HIV-1 infection immediately prior to initiating emtricitabine and tenofovir disoproxil fumarate tablets for HIV-1 PrEP and at least once every 3 months while taking emtricitabine and tenofovir disoproxil fumarate tablets, and upon diagnosis of any other sexually transmitted infections (STIs) [see Indications and Usage (1.2), Contraindications (4), and Warnings and Precautions (5.2)].

If recent (<1 month) exposures to HIV-1 are suspected or clinical symptoms consistent with acute HIV-1 infection are present, use a test approved or cleared by the FDA as an aid in the diagnosis of acute or primary HIV-1 infection [see Warnings and Precautions (5.2)]. Use in Specific Populations (8.4).

2.3 Recommended Dosage for Treatment of HIV-1 Infection in Adults and Pediatric Patients Weighing at Least 35 kg
Emtricitabine and tenofovir disoproxil fumarate tablets are a two-drug fixed dose combination product containing emtricitabine (FTC) and tenofovir disoproxil fumarate (TDF). The recommended dosage of emtricitabine and tenofovir disoproxil fumarate tablets in adults and in pediatric patients weighing at least 35 kg is one tablet (containing 200 mg of FTC and 300 mg of TDF) once daily taken orally with or without food [see Clinical Pharmacology (12.3)].

2.4 Recommended Dosage for Treatment of HIV-1 Infection in Pediatric Patients Weighing at Least 17 kg and Able to Swallow a Tablet
The recommended oral dosage of emtricitabine and tenofovir disoproxil fumarate tablets for pediatric patients weighing at least 17 kg and who can swallow a tablet is presented in Table 1. Tablets should be taken once daily with or without food. Weight should be monitored periodically and the emtricitabine and tenofovir disoproxil fumarate tablets should be discontinued if underweight.

2.5 Recommended Dosage for HIV-1 PrEP in Adults and Adolescents Weighing at Least 35 kg
The recommended oral dosage of emtricitabine and tenofovir disoproxil fumarate tablets for adult and adolescent patients weighing at least 35 kg is one tablet (containing 200 mg of FTC and 300 mg of TDF) once daily taken orally with or without food in HIV-1 uninfected adults and adolescents weighing at least 35 kg [see Clinical Pharmacology (12.3)].

2.6 Dosage Adjustment for HIV-1 PrEP in Individuals with Renal Impairment
Treatment of HIV-1 Infection
Table 2 provides dosage interval adjustment for patients with renal impairment. No dosage adjustment is necessary for HIV-1 infected patients with mild renal impairment (creatinine clearance 30 to 49 mL/min). The safety and effectiveness of the dosage interval adjustment recommendations in patients with moderate renal impairment (creatinine clearance 30 to 49 mL/min) have not been clinically evaluated; however, clinical response and benefits of continued use [see Warnings and Precautions (5.3)].

Table 2 Dosage Interval Adjustment for HIV-1 Infected Adult Patients with Altered Creatinine Clearance

Body Weight (kg)

17 to less than 22

22 to less than 28

28 to less than 35

35 to less than 49

49 to less than 67

67 to less than 85

85 to less than 103

103 to less than 121

121 to less than 139

139 to less than 157

157 to less than 175

175 to less than 193

193 to less than 211

211 to less than 229

229 to less than 247

247 to less than 265

265 to less than 283

283 to less than 301

301 to less than 319

319 to less than 337

337 to less than 355

355 to less than 373

373 to less than 391

391 to less than 409

409 to less than 427

427 to less than 445

445 to less than 463

463 to less than 481

481 to less than 499

499 to less than 517

517 to less than 535

535 to less than 553

553 to less than 571

571 to less than 589

589 to less than 607

607 to less than 625

625 to less than 643

643 to less than 661

661 to less than 679

679 to less than 697

697 to less than 715

715 to less than 733

733 to less than 751

751 to less than 769

769 to less than 787

787 to less than 805

805 to less than 823

823 to less than 841

841 to less than 859

859 to less than 877

877 to less than 895

895 to less than 913

913 to less than 931

931 to less than 949

949 to less than 967

967 to less than 985

985 to less than 1003

1003 to less than 1021

1021 to less than 1039

1039 to less than 1057

1057 to less than 1075

1075 to less than 1093

1093 to less than 1111

1111 to less than 1129

1129 to less than 1147

1147 to less than 1165

1165 to less than 1183

1183 to less than 1201

1201 to less than 1219

1219 to less than 1237

1237 to less than 1255

1255 to less than 1273

1273 to less than 1291

1291 to less than 1309

1309 to less than 1327

1327 to less than 1345

1345 to less than 1363

1363 to less than 1381

1381 to less than 1399

1399 to less than 1417

1417 to less than 1435

1435 to less than 1453

1453 to less than 1471

1471 to less than 1489

1489 to less than 1507

1507 to less than 1525

1525 to less than 1543

1543 to less than 1561

1561 to less than 1579

1579 to less than 1597

1597 to less than 1615

1615 to less than 1633

1633 to less than 1651

1651 to less than 1669

1669 to less than 1687

1687 to less than 1705

1705 to less than 1723

1723 to less than 1741

1741 to less than 1759

1759 to less than 1777

1777 to less than 1795

1795 to less than 1813

1813 to less than 1831

1831 to less than 1849

1849 to less than 1867

1867 to less than 1885

1885 to less than 1903

1903 to less than 1921

1921 to less than 1939

1939 to less than 1957

1957 to less than 1975

1975 to less than 1993

1993 to less than 2011

2011 to less than 2029

2029 to less than 2047

2047 to less than 2065

2065 to less than 2083

2083 to less than 2101

2101 to less than 2119

2119 to less than 2137

2137 to less than 2155

2155 to less than 2173

2173 to less than 2191

2191 to less than 2209

2209 to less than 2227

2227 to less than 2245

2245 to less than 2263

2263 to less than 2281

2281 to less than 2299

2299 to less than 2317

2317 to less than 2335

2335 to less than 2353

2353 to less than 2371

2371 to less than 2389

2389 to less than 2407

2407 to less than 2425

2425 to less than 2443

2443 to less than 2461

2461 to less than 2479

2479 to less than 2497

2497 to less than 2515

2515 to less than 2533

2533 to less than 2551

2551 to less than 2569

