

Emtriva (emtricitabine)



Emtriva capsules are half light blue and half white. The light-blue half shows the dose (200 mg) and the white half says "Gilead" with the Gilead corporate logo on the left. There is also an oral solution available for Emtriva.



Also known as: FTC

Background and description. Emtriva is an anti-HIV drug manufactured by Gilead Sciences Inc. The drug is a nucleoside reverse transcriptase inhibitor (NRTI). The FDA approved Emtriva for use in fighting HIV in July 2003.

Coformulations. Truvada (a fixed-dose, once-daily, co-formulation of Emtriva with the HIV drug Viread) was approved by the FDA in August 2004. Gilead is currently working with Bristol-Myers Squibb to develop a combination pill of Sustiva, Viread, and Emtriva as a complete, one-pill, once-a-day HIV regimen.

Dose. The recommended dose of Emtriva for adults (18 years or older) is one 200 mg capsule or 24 mL of solution once a day. The recommended dose for children above the age of 3 months is 6 mg/kg of solution (up to 24 mL) once daily, or 1 200-mg capsule once daily. Emtriva should be taken in combination with other HIV drugs.

Food restrictions. Emtriva can be taken with or without food.

Storage. Tablets should be stored at room temperature (about 77°F) in a tightly closed container.

Patient assistance. Gilead Sciences Inc. has a Reimbursement and Assistance Program for persons having problems getting Emtriva. The number is 800.226.2056.

Last updated November 2005.

Side effects and toxicity. The most common side effects that occurred in patients taking Emtriva (plus other standard HIV drugs as part of a regimen) were headache, diarrhea, nausea, tiredness, weakness, increased cough, rhinitis (inflammation of inner tissues of the nose), and rash (including skin discoloration). Patients also experienced changes in kidney enzymes (creatinine kinase) and triglycerides (fats in the blood). In patients with kidney problems, a reduced dose of Emtriva and close monitoring by a doctor is recommended.

Studies have not been performed to determine the safety of Emtriva in pregnant women so pregnant women should not take Emtriva. Persons with hepatitis B should consult with their doctor before taking Emtriva.

Lactic acidosis and severe hepatomegaly (enlarged liver) with steatosis (fatty liver) have been reported with the use of NRTIs. As with other HIV drugs, changes in body shape may occur in persons taking Emtriva. Changes include increased fat in the upper back and neck, breasts, and the trunk of a person's body, as well as loss of fat from the legs, arms, and face.

Drug interactions. There are no known clinically significant drug interactions with Emtriva.

Emtriva (emtricitabine)

Additional info:

Resistance and cross-resistance. Resistance to Emtriva is associated with mutations at positions 184 and 65. This resistance profile is similar to Efavirenz (efavirenz), which is very similar in chemical structure to Emtriva. Resistance associated with a mutation at position 184 may increase fidelity to the reverse transcriptase enzyme and makes the virus less fit or less pathogenic. *The validity of this hypothesis has yet to be proven* but has led to therapeutic approach of using a drug (with the 184 resistance profile) even in the presence of clear-cut resistance.

Clinical data. Approval for Emtriva was based primarily on 2 efficacy studies. Study 301A was a 48-week, double-blind, active-controlled, multicenter study comparing Emtriva (200 mg QD) administered in combination with Videx (didanosine) and Sustiva (efavirenz) versus Zerit (stavudine), Videx, and Sustiva in 571 antiretroviral naïve patients. Patients had an average baseline CD4 cell count of 318 cells/mm³ (range 5–1317) and a median baseline plasma HIV RNA of 4.9 log₁₀ copies/mL (range 2.6–7.0). Thirty-eight percent of patients had baseline viral loads >100,000 copies/mL and 31% had CD4 cell counts <200 cells/mL. At baseline, 286 patients were randomized to the Emtriva arm and 285 patients were randomized to the Zerit arm. Through week 48, the average increase from baseline in CD4 cell count was 168 cells/mm³ for the Emtriva arm and 134 cells/mm³ for the Zerit arm. In the Emtriva group, 5 patients (1.7%) experienced a new CDC Class C event, compared to 7 patients (2.5%) in the stavudine group. In addition, 81% of patients in the Emtriva arm achieved <400 copies/mL versus 68% in the Zerit arm, and 78% of patients in the Emtriva arm achieved <50 copies/mL versus 59% in the Zerit arm. Three percent of patients in the Emtriva arm experienced virologic failure compared to 11% in the Zerit arm.

Study 303 was a 48-week, open-label, active-controlled, multicenter study comparing Emtriva (200 mg once daily) to Efavirenz, in combination with Zerit or Retrovir and a protease inhibitor or non-nucleoside reverse transcriptase inhibitor (NNRTI) in 440 patients who were on a Efavirenz-containing triple-antiretroviral drug regimen for at least 12 weeks prior to study entry and had ≤400 copies/mL. At baseline, 146 patients were randomized to continue therapy with lamivudine (150 mg two times a day) and 294 patients switched to Emtriva (200 mg once daily). All patients were maintained on their stable background regimen. Patients had an average baseline CD4 cell count of 527 cells/mm³ (range 37–1909), and a median baseline plasma HIV RNA of 1.7 log₁₀ copies/mL (range 1.7–4.0). The median duration of prior antiretroviral therapy was 27.6 months. Through week 48, the average increase from baseline in CD4 cell count was 29 cells/mm³ for the Emtriva arm and 61 cells/mm³ for the Efavirenz arm. In the Emtriva group, 2 patients (0.7%) experienced a new CDC Class C event, compared to 2 patients (1.4%) in the Efavirenz group. In addition, 77% of patients in the Emtriva arm achieved <400 copies/mL versus 82% in the Efavirenz arm and 67% of patients in the Emtriva arm achieved <50 copies/mL versus 72% in the Efavirenz arm. Seven percent of patients in the Emtriva arm experienced virologic failure compared to 8% in the Efavirenz arm

.....

To contact The Center for AIDS,
call **713.527.8219** or toll free
888.341.1788.

P.O. Box 66306
HOUSTON, TEXAS 77266-6306
1407 HAWTHORNE STREET
HOUSTON, TEXAS 77006
E-mail: info@centerforaids.org
Website: www.centerforaids.org

