Emtricitabine (FTC, Emtriva)

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Formulations

Pediatric Oral Solution: 10 mg/mL
Capsule: 200 mg
Fixed-Dose Combination (FDC) Tablets
• [Generic] Efavirenz 600 mg/emtricitabine 200 mg/tenofovir disoproxil fumarate 300 mg
• [Biktarvy]
  o Bictegravir 50 mg/emtricitabine 200 mg/tenofovir alafenamide 25 mg
  o Bictegravir 30 mg/emtricitabine 120 mg/tenofovir alafenamide 15 mg
• [Complera] Emtricitabine 200 mg/rilpivirine 25 mg/tenofovir disoproxil fumarate 300 mg
• [Descovy]
  o Emtricitabine 200 mg/tenofovir alafenamide 25 mg
  o Emtricitabine 120 mg/tenofovir alafenamide 15 mg
• [Genvoya] Elvitegravir 150 mg/cobicistat 150 mg/emtricitabine 200 mg/tenofovir alafenamide 10 mg
• [Odefsey] Emtricitabine 200 mg/rilpivirine 25 mg/tenofovir alafenamide 25 mg
• [Stribild] Elvitegravir 150 mg/cobicistat 150 mg/emtricitabine 200 mg/tenofovir disoproxil fumarate 300 mg
• [Symtuza] Darunavir 800 mg/cobicistat 150 mg/emtricitabine 200 mg/tenofovir alafenamide 10 mg
• [Truvada]
  o Emtricitabine 200 mg/tenofovir disoproxil fumarate 300 mg
  o Emtricitabine 167 mg/tenofovir disoproxil fumarate 250 mg
  o Emtricitabine 133 mg/tenofovir disoproxil fumarate 200 mg
  o Emtricitabine 100 mg/tenofovir disoproxil fumarate 150 mg
When using FDC tablets, refer to other sections of the Drug Appendix for information about the individual components of the FDC. See also Appendix A, Table 2. Antiretroviral Fixed-Dose Combination Tablets and Co-packaged Formulations: Minimum Body Weights and Considerations for Use in Children and Adolescents.
For additional information, see Drugs@FDA or DailyMed.

Dosing Recommendations	Selected Adverse Events
Neonatal and Infant (Aged 0 to <3 Months) Dose *Oral Solution* • Emtricitabine (FTC) 3 mg/kg once daily	• Hyperpigmentation/skin discoloration on palms and/or soles

Child (Aged ≥3 Months) and Adolescent Dose

Oral Solution

- FTC 6 mg/kg once daily (maximum 240 mg per dose). The maximum dose of oral solution is higher than the capsule dose because a pediatric pharmacokinetic analysis reported that the plasma exposure for FTC was 20% lower in children who received the oral solution than in children who received the capsule formulation.

Capsules (for Children Weighing >33 kg)

- FTC 200 mg once daily

Adult Dose

Oral Solution for People Who Are Unable to Swallow Capsules

- FTC 240 mg (24 mL) once daily

Capsules

- FTC 200 mg once daily

[Generic] Efavirenz (EFV)/FTC/Tenofovir Disoproxil Fumarate (TDF)

Child and Adolescent (Weighing ≥40 kg) and Adult Dose

- One tablet once daily
- Take on an empty stomach.

[Biktarvy] Bictegravir/FTC/Tenofovir Alafenamide (TAF)

Neonate or Child (Aged <2 Years and Weighing <14 kg) Dose

- No data are available on the appropriate dose of Biktarvy in children aged <2 years and weighing <14 kg. Studies are currently being conducted to identify the appropriate dose for this age and weight group.

Child, Adolescent, and Adult Dose

- One tablet once daily, with or without food.

Body Weight	Dose
≥14 kg to <25 kg	Bictegravir 30 mg/emtricitabine 120 mg/tenofovir alafenamide 15 mg
≥25 kg	Bictegravir 50 mg/emtricitabine 200 mg/tenofovir alafenamide 25 mg

Special Instructions

- Although FTC can be administered without regard to food, some FDC tablet formulations that contain FTC have food requirements.
- FTC oral solution can be kept at room temperature, up to 77°F (25°C), if used within 3 months; refrigerate oral solution for long-term storage.
- Screen children for hepatitis B virus (HBV) infection before using FTC or FDC tablets that contain FTC. Severe acute exacerbation of HBV infection can occur when FTC is discontinued; therefore, hepatic function and hepatitis B viral load should be monitored for several months after children with HBV infection stop taking FTC.

Metabolism/Elimination

- No CYP interactions
- Eighty-six percent of FTC is excreted in urine. FTC may compete with other compounds that undergo renal elimination.

FTC Dosing in Children With Hepatic Impairment

- EFV/FTC/TDF should be used with caution in children with hepatic impairment.
- Biktarvy, Genvoya, Stribild, and Symtuza are not recommended for use in children with severe hepatic impairment.
- Complera, Descovy, and Odefsey do not require dose adjustment in mild or moderate hepatic impairment but should not be used in children with severe hepatic impairment because they have not been studied in this group.

FTC Dosing in Children With Renal Impairment

- Decrease the dose of FTC in children with impaired renal function. Consult the manufacturer's prescribing information for recommended dose adjustments.

- The U.S. Food and Drug Administration approved Biktarvy for use only in people who are antiretroviral therapy (ART)–naive or to replace the current antiretroviral (ARV) regimen in people who have been virologically suppressed (HIV RNA <50 copies/mL) on a stable ARV regimen with no history of treatment failure and no known mutations associated with resistance to the individual components of Biktarvy. Some members of the Panel on Antiretroviral Therapy and Medical Management of Children Living With HIV recommend the use of Biktarvy in children with prior treatment failure and who have virus containing the M184V mutation.
- See the Bictegravir section for additional information.

[Complera] FTC/Rilpivirine (RPV)/TDF

Child and Adolescent (Aged ≥12 Years and Weighing ≥35 kg) and Adult Dose

- One tablet once daily in people who are ART-naive who have baseline plasma HIV RNA ≤100,000 copies/mL. This dose of Complera also can be used to replace a stable ARV regimen in people who are currently on their first or second regimen and who have been virologically suppressed (HIV RNA <50 copies/mL) with no history of treatment failure and no known mutations associated with resistance to the individual components of Complera.
- Administer with a meal of at least 500 calories.

[Descovy] FTC/TAF

Child, Adolescent, and Adult Dose

Body Weight	Dose
≥14 kg to <25 kg	FTC 120 mg/TAF 15 mg, in combination with an integrase strand transfer inhibitor (INSTI) or a non-nucleoside reverse transcriptase inhibitor (NNRTI). In this weight band, Descovy should not be used with protease inhibitors (PIs) that require a cytochrome P450 (CYP) 3A inhibitor (e.g., ritonavir [RTV] or cobicistat [COBI]).
≥25 kg to <35 kg	FTC 200 mg/TAF 25 mg, in combination with an INSTI or an NNRTI. In this weight band, Descovy should not be used with PIs that require a CYP3A inhibitor (i.e., RTV or COBI).
≥35 kg	FTC 200 mg/TAF 25 mg, in combination with an INSTI, NNRTI, or boosted PI.

- **Do not use** the FDC tablets EFV/FTC/TDF or Complera in children with creatinine clearance (CrCl) <50 mL/min or in children who require dialysis.
- **Do not use** the FDC tablets Truvada or Biktarvy in children with CrCl <30 mL/min. Do not use Truvada in children who require dialysis.
- Stribild should not be initiated in children with estimated CrCl <70 mL/min and should be discontinued in children with estimated CrCl <50 mL/min.
- TAF-containing formulations are not recommended for use in children with estimated CrCl <30 mL/min.

[Genvoya] Elvitegravir (EVG)/COBI/FTC/TAF

Child and Adolescent (Weighing ≥25 kg) and Adult Dose

- One tablet once daily with food in people who are ART-naive. This dose of Genvoya also can be used to replace the current ARV regimen in people who have been virologically suppressed (HIV RNA <50 copies/mL) on a stable ARV regimen with no history of treatment failure and no known mutations associated with resistance to the individual components of Genvoya.

[Odefsey] FTC/RPV/TAF

Child and Adolescent (Aged ≥12 Years and Weighing ≥25 kg) and Adult Dose

- One tablet once daily in people who are ART-naive with HIV RNA ≤100,000 copies/mL. This dose of Odefsey also can be used to replace the current ARV regimen in people who have been virologically suppressed (HIV RNA <50 copies/mL) with no history of treatment failure and no known mutations associated with resistance to the individual components of Odefsey.
- Administer with a meal of at least 500 calories.

[Stribild] EVG/COBI/FTC/TDF

Child and Adolescent (Weighing ≥35 kg With a Sexual Maturity Rating of 4 or 5) and Adult Dose

- One tablet once daily with food in people who are ART-naive. This dose of Stribild also can be used to replace the current ARV regimen in people who have been virologically suppressed (HIV RNA <50 copies/mL) with no history of treatment failure and no known mutations associated with resistance to the individual components of Stribild.

[Symtuza] Darunavir (DRV)/COBI/FTC/TAF

Child and Adolescent (Weighing ≥40 kg) and Adult Dose

- One tablet once daily with food in people who are ART-naive or in people who have been virologically suppressed (HIV RNA <50 copies/mL) with no known mutations associated with resistance to DRV or tenofovir.

[Truvada] FTC/TDF

Child, Adolescent, and Adult Dose

Body Weight	FTC/TDF Tablet Once Daily
17 kg to <22 kg	One FTC 100 mg/TDF 150 mg tablet
22 kg to <28 kg	One FTC 133 mg/TDF 200 mg tablet
28 kg to <35 kg	One FTC 167 mg/TDF 250 mg tablet
≥35 kg and adults	One FTC 200 mg/TDF 300 mg tablet

Drug Interactions

Additional information about drug interactions is available in the Adult and Adolescent Antiretroviral Guidelines and the HIV Drug Interaction Checker.

- *Other nucleoside reverse transcriptase inhibitors (NRTIs):* **Do not use** emtricitabine (FTC) in combination with lamivudine (3TC), because these agents share similar resistance profiles and lack additive benefit. **Do not use FTC** with fixed-dose combination (FDC) medications that contain 3TC or FTC. See Appendix A, Table 1. Antiretrovirals Available in Fixed-Dose Combination Tablets or as a Co-packaged Formulation, by Drug Class, and refer to other sections of the Drug Appendix for drug interaction information for each individual component of an FDC tablet.
- *Renal elimination:* FTC may compete with other compounds that undergo renal tubular secretion. Drugs that decrease renal function could decrease clearance of FTC.

Major Toxicities

- *More common:* Headache, insomnia, diarrhea, nausea, rash. Hyperpigmentation/skin discoloration, which may be more common in children than in adults.
- *Less common (more severe):* Neutropenia. Lactic acidosis and severe hepatomegaly with steatosis, including fatal cases, have been reported. Exacerbations of hepatitis have occurred in people with hepatitis B virus (HBV)/HIV coinfection who switched from regimens that included FTC to regimens that did not include FTC.

Resistance

The International Antiviral Society–USA maintains a list of HIV drug resistance mutations, and the Stanford University HIV Drug Resistance Database offers a discussion of each mutation.

Pediatric Use

Approval

FTC is approved by the U.S. Food and Drug Administration for once-daily administration in children, starting at birth. FTC often is used as part of a dual-NRTI backbone in antiretroviral (ARV) regimens for children and adolescents because of its once-daily dosing, minimal toxicity, and favorable pediatric pharmacokinetic (PK) data.

Efficacy and Pharmacokinetics

Comparative Clinical Trials

Studies that assess the efficacy and/or potency of nucleoside/nucleotide analogues have been more concerned with the dynamic components of the regimen—such as tenofovir disoproxil fumarate (TDF), tenofovir alafenamide, or abacavir—than the more static components, such as FTC or 3TC. FTC and 3TC have been considered interchangeable, but data to support this conclusion are lacking. Investigators studying the AIDS Therapy Evaluation in the Netherlands (ATHENA) cohort compared the efficacy of TDF plus FTC with TDF plus 3TC when these drugs were administered with a ritonavir-boosted protease inhibitor (darunavir, atazanavir, or lopinavir) in participants who were antiretroviral therapy (ART)–naive.[1] The adjusted hazard ratio for the virologic

failure of 3TC-containing regimens compared with FTC-containing regimens within 240 weeks of starting therapy was 1.15 (95% confidence interval, 0.58–2.27). No difference between these regimens was observed in the time to virologic suppression during the first 48 weeks of therapy or time to virologic failure after attaining suppression. A Swiss cohort study found a potential difference in efficacy between FTC and 3TC; however, the difference disappeared after adjusting for pill burden.[2] Current evidence suggests that FTC and 3TC have equivalent efficacy and toxicity in people without ARV experience.

Efficacy

Following a dose-finding study (described in the Pharmacokinetics: Liquid Versus Capsule section below),[3] a once-daily dose of FTC 6 mg/kg administered in combination with other ARV drugs was studied in 116 infants, children, and adolescents aged 3 months to 16 years.[4] The study used a maximum dose of 240 mg of the FTC liquid formulation. PK results showed that the plasma exposures seen in these children and adolescents were similar to those seen in adults who received FTC 200 mg once daily. Follow-up data extending to Week 96 indicated that 89% of ART-naive children and 76% of ARV-experienced children maintained plasma HIV RNA <400 copies/mL (75% of ARV-naive children and 67% of ARV-experienced children had HIV RNA <50 copies/mL). Minimal toxicity was observed during this trial. The Pediatric AIDS Clinical Trials Group (PACTG) P1021 trial[5] evaluated the use of FTC 6 mg/kg (with a maximum dose of FTC 200 mg per day of the liquid formulation) as part of a three-drug regimen dosed once daily to ARV-naive children aged 3 months to 21 years. In this trial, 85% of children achieved HIV RNA <400 copies/mL, and 72% of children maintained virologic suppression (HIV RNA <50 copies/mL) through 96 weeks of therapy. The median CD4 T lymphocyte count rose by 329 cells/mm^3 at Week 96.

Pharmacokinetics: Liquid Versus Capsule

A single-dose PK study of the FTC oral solution and FTC capsules enrolled 25 children with HIV aged 2 years to 17 years.[3] FTC was found to be well absorbed following oral administration, with a mean elimination half-life of 11 hours (range 9.7–11.6 hours). Plasma concentrations in children who received the once-daily dose of FTC 6 mg/kg were approximately equivalent to those seen in adults who received the standard dose of FTC 200 mg. However, plasma concentrations of FTC after administration of the capsule formulation were approximately 20% higher than those observed after administration of the oral solution in this small cohort of children.

Pharmacokinetics in Infants

A study in South Africa evaluated the PK of FTC in 20 infants aged <3 months with perinatal HIV exposure. The participants received a dose of FTC 3 mg/kg once daily for two 4-day courses, separated by an interval of ≥2 weeks.[6] FTC exposure (area under the curve [AUC]) in neonates receiving FTC 3 mg/kg once daily was within the range of exposures seen in children aged >3 months who received the recommended dose of FTC 6 mg/kg once daily and adults who received the recommended dose of FTC 200 mg once daily. During the first 3 months of life, FTC AUC decreased with increasing age, correlating with an increase in total body clearance of the drug. In a small group of neonates (n = 6) who received a single dose of FTC 3 mg/kg and whose mothers received a single dose of FTC 600 mg during delivery, the FTC AUC exceeded the AUC seen in adults and older children. However, FTC had a half-life of 9.2 hours in these neonates, which is similar to that observed in adults and older children.[7] Extensive safety data are lacking for this age range.

Considerations for Use

The FTC oral solution has an advantage over the liquid formulation of 3TC because it can be given once daily at ARV initiation, whereas the liquid formulation of 3TC needs to be given twice daily at ARV initiation. When pill formulations of 3TC or FTC are used, they can be administered once daily.

Both FTC and 3TC have antiviral activity and efficacy against HBV. For a comprehensive review of this topic, see the Hepatitis B Virus section in the Pediatric Opportunistic Infection Guidelines.

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