

Appendix A, Table 2. Antiretroviral Fixed-Dose Combination Tablets and Co-packaged Formulations: Minimum Body Weights and Considerations for Use in Children and Adolescents

Updated: Apr.11, 2022
Reviewed: Apr.11, 2022

General Considerations When Using Fixed-Dose Combination Tablets

- For children weighing ≥ 14 kg, bicitegravir (BIC) is available as the single-tablet, once-daily regimen bicitegravir/emtricitabine/tenofovir alafenamide (BIC/FTC/TAF) (Biktarvy).
- For children weighing ≥ 25 kg, BIC, dolutegravir (DTG), and elvitegravir (EVG) are available as single-tablet, once-daily regimens as BIC/FTC/TAF (Biktarvy), abacavir/dolutegravir/lamivudine (ABC/DTG/3TC) (Triumeq), and elvitegravir/cobicistat/emtricitabine/tenofovir alafenamide (EVG/c/FTC/TAF) (Genvoya).
- BIC and DTG, second-generation integrase strand transfer inhibitors (INSTIs), have a higher barrier to resistance than the first-generation INSTI EVG.
- EVG/c/FTC/TAF (Genvoya) has more drug–drug interactions than ABC/DTG/3TC (Triumeq) or BIC/FTC/TAF (Biktarvy).
- Abacavir (ABC) or tenofovir alafenamide (TAF) in combination with lamivudine (3TC) or emtricitabine (FTC) are favored over zidovudine/lamivudine (ZDV/3TC) because of the lower risk of nucleoside reverse transcriptase inhibitor (NRTI)–associated mitochondrial toxicity.
- Tenofovir disoproxil fumarate (TDF) is more potent than ABC at high viral loads when used in regimens that do not contain an INSTI.
- TAF is favored over TDF because of the lower risk of TDF-associated bone and renal toxicity.
- TDF is not recommended for children with sexual maturity ratings (SMRs) of 1 to 3 because of TDF-associated bone toxicity. For children weighing ≥ 14 kg to < 25 kg who can swallow pills, (FTC/TAF) (Descovy) offers a once-daily alternative to twice-daily ZDV plus 3TC or ABC plus 3TC. For children weighing ≤ 35 kg, FTC/TAF (Descovy) can be used in combination with an INSTI or NNRTI, but not with a protease inhibitor; this restriction does not apply to regimens containing ZDV or ABC.
- The fixed-dose combination (FDC) tablet DOR/3TC/TDF is approved by the U.S. Food and Drug Administration (FDA) for children and adolescents weighing ≥ 35 kg who are antiretroviral (ARV) naive or virologically suppressed on a stable ARV regimen (see the [Doravirine](#) section).
- Rilpivirine (RPV) has low potency at high viral loads, a low barrier to resistance, and requires a high-fat meal for optimal absorption, so EFV or an INSTI are favored over RPV.

- The possibility of planned and unplanned pregnancy should be considered when selecting an antiretroviral therapy (ART) regimen for an adolescent. When discussing ART options with adolescents of childbearing potential and their caregivers, it is important to consider the benefits and risks of all ARV drugs and to provide the information and counseling needed to support informed decision-making (see [Table 5. Situation-Specific Recommendations for Use of Antiretroviral Drugs in Pregnant People and Nonpregnant People Who Are Trying to Conceive](#) and [Appendix C: Antiretroviral Counseling Guide for Health Care Providers](#)).
- For images of most of the FDC tablets listed in this table, see the [Antiretroviral Medications](#) section of the National HIV Curriculum. In addition, a [resource from the United Kingdom](#) illustrates the relative sizes of FDC tablets and individual ARV drugs (see the [ARV Chart](#)). Although most of the drugs listed in that chart are the same as those in the United States, a few of the brand names are not the same as those listed in this Appendix.
- FDC tablets and individual ARV drugs also can be looked up by drug name (brand name and generic) at [DailyMed](#). Size is listed under the Ingredients and Appearance section.

Integrase Strand Transfer Inhibitor Fixed-Dose Combination Dosing for Children and Adolescents

[Bictegravir](#)

- BIC/FTC/TAF (Biktarvy) is approved for pediatric use by the FDA with two dosage strengths: one for use in children weighing 14 to <25 kg and another for children and adolescents weighing ≥25 kg and adults.

[Dolutegravir](#)

- The recommended dose of DTG for children and adolescents weighing ≥20 kg is DTG 50 mg using film-coated tablets **or** DTG 30 mg using dispersible tablets. **DTG film-coated tablets and DTG dispersible tablets are not bioequivalent and are not interchangeable on a milligram-per-milligram basis**, refer to [Dolutegravir](#) for dosing information.
 - Children weighing ≥20 kg to <25 kg who can swallow pills can be treated with DTG 50-mg film-coated tablets plus FTC/TAF (Descovy) 120 mg FTC/15 mg TAF taken orally once daily.
 - For children weighing ≥25 kg who can swallow pills, DTG 50 mg can be given as Triumeq (ABC/DTG/3TC) in one large pill taken once daily or as FTC/TAF (Descovy) 200 mg FTC/25 mg TAF plus DTG 50-mg film-coated tablets, which requires two small pills taken once daily. The FDA has approved ABC/DTG/3TC (Triumeq) for pediatric patients weighing ≥40 kg, but the Panel on Antiretroviral Therapy and Medical Management of Children Living with HIV (the Panel) recommends this FDC for use in patients weighing ≥ 25 kg.

Elvitegravir

- EVG/c/FTC/TAF (Genvoya) is approved by the FDA for children and adolescents weighing ≥ 25 kg.

FDC by Class Brand name and generic ^a products, when available	FDC Components	Minimum Body Weight or Weight Range (kg) or Age ^b	Pill Size (mm × mm) or Largest Dimension (mm)	Food Requirements
NRTI				
Cimduo	3TC 300 mg/TDF 300 mg	35 kg	19	Take with or without food.
Combivir and Generic 3TC/ZDV	3TC 150 mg/ZDV 300 mg (scored tablet)	30 kg	18 × 7	Take with or without food.
Descovy	FTC 120 mg/TAF 15 mg	With an INSTI or NNRTI • 14 to < 25 kg	N/A	Take with or without food.
	FTC 200 mg/TAF 25 mg	With an INSTI or NNRTI • 25 kg With a Boosted PI • 35 kg	12.5 × 6.4	Take with or without food.
Epzicom and Generic ABC/3TC	ABC 600 mg/3TC 300 mg	25 kg	21 × 9	Take with or without food.
Temixys	3TC 300 mg/TDF 300 mg	35 kg	N/A	Take with or without food.
Truvada	FTC 100 mg/TDF 150 mg	17 to <22 kg	14	Take with or without food.
	FTC 133 mg/TDF 200 mg	22 to <28 kg	16	Take with or without food.
	FTC 167 mg/TDF 250 mg	28 to <35 kg	18	Take with or without food.
	FTC 200 mg/TDF 300 mg	35 kg	19 × 8.5	Take with or without food.
NRTI/NNRTI				
Atripla	EFV 600 mg/FTC 200 mg/TDF 300 mg	40 kg	20	Take on an empty stomach.

FDC by Class Brand name and generic ^a products, when available	FDC Components	Minimum Body Weight or Weight Range (kg) or Age ^b	Pill Size (mm × mm) or Largest Dimension (mm)	Food Requirements
Complera	FTC 200 mg/RPV 25 mg/TDF 300 mg	35 kg and aged ≥12 years	19	Take on an empty stomach.
Delstrigo	DOR 100 mg/3TC 300 mg/TDF 300 mg	35 kg	19	Take with or without food.
Odefsey	FTC 200 mg/RPV 25 mg/TAF 25 mg	35 kg and aged ≥12 years	15	Take with a meal.
Symfi	EFV 600 mg/3TC 300 mg/TDF 300 mg (scored tablet)	40 kg	23	Take on an empty stomach.
Symfi Lo	EFV 400 mg/3TC 300 mg/TDF 300 mg	35 kg ^c	21	Take on an empty stomach.
NRTI/INSTI				
Biktarvy	BIC 30 mg/FTC 120 mg/TAF 15 mg	14 to <25 kg	N/A	Take with or without food.
	BIC 50 mg/FTC 200 mg/TAF 25 mg	25 kg	15 × 8	Take with or without food.
Dovato	DTG 50 mg/3TC 300 mg	Adults ^d	19	Take with or without food.
Triumeq	ABC 600 mg/DTG 50 mg/3TC 300 mg	40 kg (FDA) 25 kg (the Panel) ^e	22 × 11	Take with or without food.
NNRTI/INSTI				
Cabenuva ^f	Cabenuva 400 mg/600 mg kit contains CAB 400 mg/2 mL vial and RPV 600 mg/2 mL vial	Adults	N/A	See Cabotegravir for instructions about dosing and administration.
	Cabenuva 600 mg/900 mg kit contains CAB 600 mg/3 mL vial and RPV 900 mg/3 mL vial	Adults	N/A	See Cabotegravir for instructions about dosing and administration.
Juluca	DTG 50 mg/RPV 25 mg	Adults ^d	14	Take with a meal.
NRTI/INSTI/COBI				
Genvoya	EVG 150 mg/COBI 150 mg/FTC 200 mg/TAF 10 mg	25 kg	19 × 8.5	Take with food.
Stribild	EVG 150 mg/COBI 150 mg/FTC 200 mg/TDF 300 mg	35 kg and SMR 4 or 5 ^g	20	Take with food.
NRTI/PI/COBI				
Symtuza	DRV 800 mg/COBI 150 mg/FTC 200 mg/TAF 10 mg	40 kg	22	Take with food.
PI/COBI				
Evotaz	ATV 300 mg/COBI 150 mg	35 kg	19	Take with food.
Prezcobix	DRV 800 mg/COBI 150 mg	40 kg	23	Take with food.

FDC by Class Brand name and generic ^a products, when available	FDC Components	Minimum Body Weight or Weight Range (kg) or Age ^b	Pill Size (mm × mm) or Largest Dimension (mm)	Food Requirements
PI/RTV				
Kaletra	LPV/r Oral Solution <ul style="list-style-type: none"> LPV 80 mg/mL and RTV 20 mg/mL Tablets <ul style="list-style-type: none"> LPV 200 mg/RTV 50 mg LPV 100 mg/RTV 25 mg 	Post-Menstrual Age of 42 Weeks and a Postnatal Age of ≥14 Days <ul style="list-style-type: none"> No minimum weight 	19	Take with or without food.

^a Sizes or largest dimensions of generic drugs are not listed because they may vary by manufacturer; this information is available by looking up one of the drug components using [DailyMed](#).

^b Minimum body weight and age are those recommended by the FDA, unless otherwise noted.

^c Because of pharmacokinetic concerns, the Panel recommends caution when using Symfi Lo in children and adolescents who have SMRs of 1 to 3 and weigh ≥40 kg (see the [Efavirenz](#) section).

^d The Panel does not currently recommend using dolutegravir/lamivudine (**DTG/3TC**) (Dovato) or dolutegravir/rilpivirine (**DTG/RPV**) (Juluca) as a two-drug complete regimen in adolescents and children. These FDC tablets could be used as part of a three-drug regimen in children who meet the minimum body weight requirements for each component drug.

^e The Panel recommends using DTG 50 mg for children and adolescents weighing ≥20 kg based on available data; however, the doses of ABC and 3TC in Triumeq are too high for children weighing <25 kg (see the [Dolutegravir](#) section).

^f Long-acting cabotegravir (CAB) and RPV for intramuscular injection are available as a co-packaged product (Cabenuva); oral formulations of CAB and RPV for initial lead-in dosing must be prescribed separately (see the [Cabotegravir](#) and [Rilpivirine](#) sections).

^g Although Stribild is approved by the FDA for use in children and adolescents weighing ≥35 kg and age ≥12 years, the Panel does not recommend its use in children with SMRs 1 to 3 given the availability of other INSTI-containing FDCs.

Key: 3TC = lamivudine; ABC = abacavir; ATV = atazanavir; BIC = bictegravir; CAB = cabotegravir; COBI = cobicistat; DOR = doravirine; DRV = darunavir; DTG = dolutegravir; EFV = efavirenz; EVG = elvitegravir; FDA = U.S. Food and Drug Administration; FDC = fixed-dose combination; FTC = emtricitabine; INSTI = integrase strand transfer inhibitor; kg = kilogram; LPV = lopinavir; LPV/r = lopinavir/ritonavir; mg = milligram; mL = milliliter; mm = millimeter; N/A = information not available or not applicable; NNRTI = non-nucleoside reverse transcriptase inhibitor; NRTI = nucleoside reverse transcriptase inhibitor; the Panel = Panel on Antiretroviral Therapy and Medical Management of Children Living with HIV; PI = protease inhibitor; RPV = rilpivirine; RTV = ritonavir; SMR = sexual maturity rating; TAF = tenofovir alafenamide; TDF = tenofovir disoproxil fumarate; ZDV = zidovudine