

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

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General Considerations When Using Fixed-Dose Combination Products

Please see the individual drug sections under [Appendix A. Pediatric Antiretroviral Drug Information](#) for the recommended dosing of individual fixed-dose combination (FDC) products.

FDC tablets and individual antiretroviral (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.

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](#) at [HIV i-BASE](#)). Although most of the drugs listed in the chart are the same as those in the United States, there are several differences: some formulations available in the United States are not included; a few of the brand names are not the same as those listed in Appendix A, Table 2; and the chart includes a formulation that is not available in the United States.

Integrase Strand Transfer Inhibitors

- Bictegravir (BIC) and dolutegravir (DTG), second-generation integrase strand transfer inhibitors (INSTIs), have a higher barrier to resistance than the first-generation INSTIs, elvitegravir (EVG) and raltegravir.
- DTG is available in multiple once-daily FDC formulations with further considerations as follows:
 - o ABC/DTG/3TC is available in two different formulations, with the appropriate formulation depending on weight. For children weighing ≥ 3 kg to < 25 kg and aged ≥ 4 weeks, ABC/DTG/3TC is available in a dispersible tablet, once-daily regimen (Triumeq PD); the number of tablets per dose depends on the child's weight. U.S. Food and Drug Administration (FDA) approval of Triumeq PD is only for children weighing ≥ 6 kg to < 25 kg and aged ≥ 3 months, but the Panel supports use in those weighing ≥ 3 kg and aged ≥ 4 weeks, based on available pharmacokinetic modeling and simulation data. For children and adolescents weighing ≥ 25 kg, ABC/DTG/3TC is available as a once-daily single-tablet regimen (Triumeq).
 - o For adolescents weighing ≥ 25 kg and aged ≥ 12 years, DTG/3TC is available as a single-tablet, once-daily regimen (Dovato).

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- o For adolescents weighing ≥ 35 kg and aged ≥ 12 years, DTG/rilpivirine (RPV) may also be considered because the dosing of the individual components aligns with dosing recommendations in this population.¹
- o If none of the FDC combinations containing DTG are options, then single-entity DTG (Tivicay, Tivicay PD) can be used in combination with other FDC tablets. Refer to the [Dolutegravir](#) section for dosing information.
- o Whether considering DTG in FDC or single-entity form, **the film-coated tablets and dispersible tablets are not bioequivalent and, thus, are not interchangeable on a milligram-per-milligram basis.**
- For children weighing ≥ 14 kg, BIC is available as the single-tablet, once-daily regimen BIC/emtricitabine (FTC)/tenofovir alafenamide (TAF) (Biktarvy). There are two dosage strengths for pediatric use: one for use in children weighing ≥ 14 kg to < 25 kg and another for children and adolescents weighing ≥ 25 kg and adults. Refer to the [Bictegravir](#) section for dosing information.
- For children weighing ≥ 25 kg, EVG is available as the single-tablet, once-daily regimen elvitegravir/cobicistat (EVG/c)/FTC/TAF (Genvoya). EVG/c/FTC/TAF (Genvoya) has more drug–drug interactions than ABC/DTG/3TC (Triumeq or Triumeq PD) or BIC/FTC/TAF (Biktarvy). Refer to the [Elvitegravir](#) section for dosing information.
- The two-drug, co-packaged regimen of long-acting injectable cabotegravir (CAB) and RPV (Cabenuva) is approved by the FDA for use in children and adolescents aged ≥ 12 years and weighing ≥ 35 kg. CAB and RPV are administered by intramuscular injection on a monthly or every-2-months schedule after an optional oral lead-in. See the [Cabotegravir](#) and [Rilpivirine](#) sections for instructions about dosing and administration.

Nucleoside/Nucleotide Reverse Transcriptase Inhibitors

- ABC or TAF in combination with 3TC or FTC are favored over zidovudine (ZDV)/3TC because of the lower risk of nucleoside/nucleotide reverse transcriptase inhibitor–associated mitochondrial toxicity.
- Tenofovir disoproxil fumarate (TDF) is more potent than ABC at high viral loads ($> 100,000$ copies/mL) 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 of 1 to 3 because of TDF-associated bone toxicity.
- For children weighing ≥ 14 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 ≥ 14 kg and ≤ 35 kg, FTC/TAF (Descovy) can be used in combination with an INSTI or non-nucleoside reverse transcriptase inhibitor but not with a protease inhibitor; this restriction does not apply to regimens containing ZDV or ABC.

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Non-nucleoside Reverse Transcriptase Inhibitors

- The FDC tablet doravirine/3TC/TDF is approved by the FDA for children and adolescents weighing ≥ 35 kg who are ARV naive or virologically suppressed on a stable ARV regimen (see the [Doravirine](#) section).
- RPV has low potency at high viral loads ($>100,000$ copies/mL) and requires a high-fat meal for optimal absorption, so INSTIs are favored over RPV.

Fixed-Dose Combinations Available for Children and Adolescents

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) ^c	Food Requirements
NRTI				
Cimduo	3TC 300 mg/TDF 300 mg	35 kg	19	Take with or without food.
Combivir^d	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^d	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.

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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)^c	Food Requirements
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^d	EFV 600 mg/FTC 200 mg/TDF 300 mg	40 kg	20	Take on an empty stomach.
Complera	FTC 200 mg/RPV 25 mg/TDF 300 mg	35 kg and aged ≥12 years	19	Take with a meal. ^e
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	25 kg and aged ≥12 years	15	Take with a meal. ^e
Symfi	EFV 600 mg/3TC 300 mg/TDF 300 mg (scored tablet)	40 kg	23	Take on an empty stomach.
Symfi Lo^d	EFV 400 mg/3TC 300 mg/TDF 300 mg	35 kg ^f	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	25 kg	19	Take with or without food.
Triumeq	ABC 600 mg/DTG 50 mg/3TC 300 mg	25 kg	22 × 11	Take with or without food.

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Triumeq PD	ABC 60 mg/DTG 5 mg/3TC 30 mg	3 to <25 kg and aged ≥1 month ^g	N/A (dispersible)	Take with or without food.
NNRTI/INSTI				
Cabenuva^h	Cabenuva 400 mg/600 mg kit contains CAB 400 mg/2 mL vial and RPV 600 mg/2 mL vial	35 kg and aged ≥12 years	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	35 kg and aged ≥12 years	N/A	See Cabotegravir for instructions about dosing and administration.
Juluca	DTG 50 mg/RPV 25 mg	35 kg and aged ≥12 years ⁱ	14	Take with a meal. ^e
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 of 4 or 5 ^j	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.

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PI/COBI				
Evotaz	ATV 300 mg/COBI 150 mg	35 kg	19	Take with food.
Prezcobix	DRV 600 mg/COBI 90 mg	15 to <25 kg and aged ≥3 years	21	Take with food.
	DRV 675 mg/COBI 150 mg	25 to <40 kg	21	Take with food.
	DRV 800 mg/COBI 150 mg	40 kg	23	Take with food.
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 	Postmenstrual 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 The possibility of planned and unplanned pregnancy should be considered when selecting an ART regimen for an adolescent. When discussing ART options with adolescents and their caregivers, it is important to consider childbearing potential and the benefits and risks of all ARV drugs and to provide the information and counseling needed to support informed decision-making (see [Table 7. Situation-Specific Recommendations for Use of Antiretroviral Drugs During Pregnancy and When Trying to Conceive](#) and [Appendix C: Antiretroviral Counseling Guide for Health Care Providers](#)).

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

^c 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](#).

^d Brand name product has been discontinued; generic version is still available.

^e Patients must be able to take oral RPV with a meal of at least 500 calories on a regular schedule (a protein drink alone does not constitute a meal).

^f Because of pharmacokinetic concerns, the Panel on Antiretroviral Therapy and Medical Management of Children Living With HIV (the Panel) recommends caution when using **EFV 400 mg/3TC 300 mg/TDF 300 mg** in children and adolescents who have SMRs of 1 to 3 and weigh ≥40 kg (see the [Efavirenz](#) section).

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^g ABC/DTG/3TC is available in dispersible tablets (Triumeq PD) and can be used in infants and children weighing ≥ 3 kg to < 25 kg and aged ≥ 1 month, with the dosage and number of tablets based on weight. FDA approval is only for those weighing ≥ 6 kg to < 25 kg and aged ≥ 3 months, but the Panel supports use in children weighing ≥ 3 kg and aged ≥ 4 weeks, based on available pharmacokinetic modeling and simulation data. Refer to the [Dolutegravir](#) section for exact dosage and instructions for administration. Dispersible tablets (Triumeq PD) **are not recommended** for children and adolescents weighing ≥ 25 kg.

^h Long-acting injectable CAB and RPV for intramuscular administration are available as a co-packaged product (Cabenuva); oral formulations of CAB and RPV for the optional initial lead-in dosing or bridging between injections > 7 days from the target injection window must be prescribed separately (see the [Cabotegravir](#) and [Rilpivirine](#) sections).

ⁱ DTG/RPV (Juluca) is not currently approved for use in adolescents with HIV; however, the doses of the component drugs that make up this FDC tablet are approved for use in adolescents. The Panel usually endorses the use of adult formulations in adolescents, and this product may be appropriate for use in certain adolescents. See [Modifying Antiretroviral Regimens in Children With Sustained Virologic Suppression on Antiretroviral Therapy](#) for additional considerations on using this combination.

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

Key: 3TC = lamivudine; ABC = abacavir; **ART = antiretroviral therapy**; 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; LPV = lopinavir; LPV/r = lopinavir/ritonavir; N/A = information not available or not applicable; NNRTI = non-nucleoside reverse transcriptase inhibitor; NRTI = nucleoside reverse transcriptase inhibitor; PI = protease inhibitor; RPV = rilpivirine; RTV = ritonavir; SMR = sexual maturity rating; TAF = tenofovir alafenamide; TDF = tenofovir disoproxil fumarate; ZDV = zidovudine