



CLINICAL GUIDELINES PROGRAM

NEW YORK STATE DEPARTMENT OF HEALTH AIDS INSTITUTE | HIV · HCV · SUBSTANCE USE · LGBT HEALTH

Selecting an Initial ART Regimen

October 2021

| Table 9: Recommended Dose Adjustments for Use of Selected Fixed-Dose Combination Antiretroviral Medications in Patients With Hepatic or Renal Impairment | | | | |
|--|---|--|---|---|
| FDC | Hepatic Impairment Dose Adjustment [a] | Recommended Dose Adjustments for Renal Impairment | | |
| | | Recommended Dose Adjustment [a] | Individual Components of FDC and Recommended Dose Adjustment [a] | Clinical Comments |
| <i>Integrase Strand Transfer Inhibitors (INSTIs)</i> | | | | |
| Abacavir/dolutegravir/lamivudine (ABC/DTG/3TC; Triumeq) See package insert | Child-Pugh A, B, C: Do not use. | CrCl <30 mL/min: Use of FDC is not recommended. | <p>ABC: No renal dose adjustment is needed.</p> <p>DTG: No renal dose adjustment is needed.</p> <p>3TC:</p> <ul style="list-style-type: none"> CrCl 30 to 49 mL/min: 150 mg once daily. CrCl 15 to 29 mL/min: 150 mg first dose then 100 mg once daily. CrCl 5 to 14 mL/min: 150 mg first dose then 50 mg once daily. CrCl <5 mL/min: 50 mg first dose then 25 mg once daily. | <p>CrCl >30 mL/min: Limited data to support use of FDC; 21 patients with CrCl >30 mL/min received full dose 3TC with minimal increases in AUC. No elevations in lactate or other ADRs reported [Fischetti, et al. 2018].</p> <p>CrCl <30 mL/min, without HD: Renal adjustment should be based on individual components; 13 patients with CrCl <30 mL/min not on HD received 100 to 150 mg of 3TC with minimal increases in AUC. No elevations in lactate or other ADRs reported [Fischetti, et al. 2018].</p> <p>CrCl <30 mL/min, with HD: Limited data to support use of FDC. Case series evaluating safety and efficacy of FDC in 9 patients with end-stage renal disease on HD reported viral suppression achieved in all 9 patients. No change in immune function. FDC generally well tolerated; one patient complained of nausea, which resolved without drug discontinuation [Michienzi, et al. 2019].</p> <p>Note: DTG serum concentrations appear to be reduced in uninfected healthy controls with eGFR <30 mL/min/m² compared to those with normal kidney function. This may increase the risk of therapeutic failure among patients with HIV drug resistance to INSTIs. [Tivicay package insert].</p> |

Table 9: Recommended Dose Adjustments for Use of Selected Fixed-Dose Combination Antiretroviral Medications in Patients With Hepatic or Renal Impairment

| FDC | Hepatic Impairment Dose Adjustment [a] | Recommended Dose Adjustments for Renal Impairment | | |
|--|--|--|--|--|
| | | Recommended Dose Adjustment [a] | Individual Components of FDC and Recommended Dose Adjustment [a] | Clinical Comments |
| Bictegravir/emtricitabine/tenofovir alafenamide [b] (BIC/FTC/TAF; Biktarvy) See package insert | Child-Pugh A, B: No dose adjustment is needed. Child-Pugh C: Do not use. | CrCl <30 mL/min: Use of FDC is not recommended. | BIC: No renal adjustment is needed. FTC: <ul style="list-style-type: none"> • CrCl 30 to 49 mL/min: 200 mg every 48 hours. • CrCl 15 to 29 mL/min: 200 mg every 72 hours. • CrCl <15 mL/min: 200 mg every 96 hours. TAF: <ul style="list-style-type: none"> • CrCl <15 mL/min, without HD: Use is not recommended. • CrCl <15 mL/min, with HD: No renal dose adjustment is needed. | CrCl <30 mL/min: No data to support use of FDC. Renal dose adjustment should be based on individual components. CrCl 15 to 29 mL/min: No BIC dose adjustment is needed. In a study of 10 patients with CrCl 15 to 29 mL/min compared to 8 patients with normal renal function who received a single dose of BIC 75 mg, severe renal impairment did not produce clinically relevant changes in BIC exposure [Zhang, et al. 2017]. |
| Elvitegravir/cobicistat/emtricitabine/tenofovir disoproxil fumarate (EVG/COBI/FTC/TDF; Stribild) See package insert | Child-Pugh A, B: No dose adjustment is needed. Child-Pugh C: No data; do not use. | CrCl <70 mL/min: Do not initiate therapy. Drop in CrCl to <50 mL/min during treatment: Discontinue therapy. | EVG: No renal dose adjustment is needed. EVG/COBI: No renal dose adjustment is needed. FTC: <ul style="list-style-type: none"> • CrCl 30 to 49 mL/min: 200 mg every 48 hours. • CrCl 15 to 29 mL/min: 200 mg every 72 hours. • CrCl <15 mL/min: 200 mg every 96 hours. TDF: <ul style="list-style-type: none"> • CrCl 30 to 49 mL/min: 300 mg every 48 hours. • CrCl 10 to 29 mL/min: 300 mg every 72 to 96 hours. • CrCl <10 mL/min, without HD: No data available. • CrCl <10 mL/min, with HD: 300 mg every 7 days. | CrCl <30 mL/min: No data to support use of FDC. Renal dose adjustment should be based on individual components. EVG/COBI: Dose adjustment not warranted. In 12 patients with eGFR <30 mL/min/m ² (not on HD) and 12 controls with normal renal function given 7 days of EVG/COBI, lower EVG AUC, C _{max} , and C _{min} values and higher COBI AUC, C _{max} , and C _{min} values were observed in severe renal impairment, but values were not considered clinically relevant [German, et al. 2012]. |

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|--|--|---|--|--|
| | | Recommended Dose Adjustment [a] | Individual Components of FDC and Recommended Dose Adjustment [a] | Clinical Comments |
| Elvitegravir/cobicistat/emtricitabine/tenofovir alafenamide [b] (EVG/COBI/FTC/TAF; Genvoya) See package insert | Child-Pugh A, B: No dose adjustment is needed. Child-Pugh C: Do not use. | CrCl <30mL/min: Use of FDC is not recommended. | EVG: No renal dose adjustment is needed. EVG/COBI: No renal dose adjustment is needed. FTC: <ul style="list-style-type: none"> • CrCl 30 to 49 mL/min: 200 mg every 48 hours. • CrCl 15 to 29 mL/min: 200 mg every 72 hours. • CrCl <15 mL/min: 200 mg every 96 hours. TAF: <ul style="list-style-type: none"> • CrCl <15 mL/min, without HD: Use is not recommended. • CrCl <15 mL/min, with HD: No renal dose adjustment is needed. • ESRD, with HD: One tablet once daily; administer after HD on HD days. | CrCl <30 mL/min, without HD: No data to support use of FDC. Renal adjustment should be based on individual components. CrCl <15 mL/min, with HD: In a study of 55 patients on FDC for up to 96 weeks, 18 (33%) had grade 3 or higher ADR during treatment, and 3 patients discontinued treatment due to adverse effects. The authors concluded that, at 48 weeks, the FDC regimen was well tolerated in patients on HD [Eron, et al. 2018]. |
| Dolutegravir/lamivudine (DTG/3TC; Dovato) See package insert | Child-Pugh A, B: No dose adjustment is needed. Child-Pugh C: Do not use. | CrCl <30 mL/min: Use of FDC is not recommended. | DTG: No renal dose adjustment is needed. 3TC: <ul style="list-style-type: none"> • CrCl 30 to 49 mL/min: 150 mg once daily. • CrCl 15 to 29 mL/min: 150 mg first dose, then 100 mg once daily. • CrCl 5 to 14 mL/min: 150 mg first dose, then 50 mg once daily. • CrCl <5 mL/min: 50 mg first dose, then 25 mg once daily. | CrCl <50mL/min: No data to support use of FDC. Renal dose adjustment should be based on individual components. |
| Dolutegravir/rilpivirine (DTG/RPV; Juluca) See package insert | Child-Pugh A, B: No dose adjustment is needed. Child-Pugh C: No data; do not use. | CrCl <30 mL/min or ESRD: No dose adjustment is needed; increased monitoring is recommended. | — | — |

Table 9: Recommended Dose Adjustments for Use of Selected Fixed-Dose Combination Antiretroviral Medications in Patients With Hepatic or Renal Impairment

| FDC | Hepatic Impairment Dose Adjustment [a] | Recommended Dose Adjustments for Renal Impairment | | |
|--|--|---|--|---|
| | | Recommended Dose Adjustment [a] | Individual Components of FDC and Recommended Dose Adjustment [a] | Clinical Comments |
| <i>Non-Nucleoside Reverse Transcriptase Inhibitor (NNRTIs)</i> | | | | |
| Emtricitabine/rilpivirine/tenofovir alafenamide (FTC/RPV/TAF; Odefsey) [b] See package insert | Child-Pugh A, B: No dose adjustment is needed. Child-Pugh C: No data. | CrCl <30 mL/min: Use of FDC is not recommended. | FTC: <ul style="list-style-type: none"> • CrCl 30 to 49 mL/min: 200 mg every 48 hours. • CrCl 15 to 29 mL/min: 200 mg every 72 hours. • CrCl <15 mL/min: 200 mg every 96 hours. RPV: No renal dose adjustment needed. TAF: <ul style="list-style-type: none"> • CrCl <15 mL/min, without HD: Use is not recommended. • CrCl <15 mL/min, with HD: No renal dose adjustment is needed. | CrCl <30 mL/min, without HD: No data to support use of FDC. Renal dose adjustment should be based on individual components. CrCl <30 mL/min, with HD: One FDC tablet once daily. On HD days, administer after dialysis [DHHS 2021]. Note: Dose recommended based on data using FTC/TAF as part of FDC with EVG/COBI in patients on HD: In a study of 55 patients on EVG/COBI/FTC/TAF for up to 96 weeks, 18 (33%) had grade 3 or higher ADRs during treatment, and 3 patients discontinued treatment due to adverse effects. The authors concluded that at 48 weeks, the FDC regimen was well tolerated in patients on HD [Eron, et al. 2018]. |
| Doravirine/lamivudine/tenofovir disoproxil fumarate (DOR/3TC/TDF; Delstrigo) See package insert | Child-Pugh A, B: No dose adjustment is needed. Child-Pugh C: No data. | CrCl <50 mL/min: Use of FDC is not recommended. | DOR: No renal dose adjustment is needed. 3TC: <ul style="list-style-type: none"> • CrCl 30 to 49 mL/min: 150 mg once daily. • CrCl 15 to 29 mL/min: 150 mg first dose, then 100 mg once daily. • CrCl 5 to 14 mL/min: 150 mg first dose, then 50 mg once daily. • CrCl <5 mL/min: 50 mg first dose, then 25 mg once daily. TDF: <ul style="list-style-type: none"> • CrCl 30 to 49 mL/min: 300 mg every 48 hours. • CrCl 10 to 29 mL/min: 300 mg every 72 to 96 hours. • CrCl <10 mL/min, without HD: No data available. • CrCl <10 mL/min, with HD: 300 mg every 7 days. | CrCl <50 mL/min: No data to support use of FDC. Renal dose adjustment should be based on individual components. |

Table 9: Recommended Dose Adjustments for Use of Selected Fixed-Dose Combination Antiretroviral Medications in Patients With Hepatic or Renal Impairment

| FDC | Hepatic Impairment Dose Adjustment [a] | Recommended Dose Adjustments for Renal Impairment | | |
|--|--|---|--|---|
| | | Recommended Dose Adjustment [a] | Individual Components of FDC and Recommended Dose Adjustment [a] | Clinical Comments |
| Efavirenz/lamivudine/tenofovir disoproxil fumarate (EFV/3TC/TDF; Symfi Lo) See package insert | Child-Pugh A: No dose adjustment is needed. Child-Pugh B, C: No data; do not use. | CrCl <50 mL/min: Use of FDC is not recommended. | EFV: No renal dose adjustment is needed. 3TC: <ul style="list-style-type: none"> • CrCl 30 to 49 mL/min: 150 mg once daily. • CrCl 15 to 29 mL/min: 150 mg first dose, then 100 mg once daily. • CrCl 5 to 14 mL/min: 150 mg first dose, then 50 mg once daily. TDF: <ul style="list-style-type: none"> • CrCl 30 to 49 mL/min: 300 mg every 48 hours. • CrCl 10 to 29 mL/min: 300 mg every 72 to 96 hours. • CrCl <10 mL/min, without HD: No data available. • CrCl <10 mL/min, with HD: 300 mg every 7 days. | CrCl <50 mL/min: No data to support use of FDC. Renal dose adjustment should be based on individual components. |
| Efavirenz/emtricitabine/tenofovir disoproxil fumarate (EFV/FTC/TDF; Atripla) See package insert | Child-Pugh A: No adjustment is needed. Child-Pugh B, C: No data; do not use. | CrCl <50 mL/min: Use of FDC is not recommended. | EFV: No renal dose adjustment is needed. FTC: <ul style="list-style-type: none"> • CrCl 30 to 49 mL/min: 200 mg every 48 hours. • CrCl 15 to 29 mL/min: 200 mg every 72 hours. • CrCl <15 mL/min: 200 mg every 96 hours. TDF: <ul style="list-style-type: none"> • CrCl 30 to 49 mL/min: 300 mg every 48 hours. • CrCl 10 to 29 mL/min: 300 mg every 72 to 96 hours. • CrCl <10 mL/min, without HD: No data available. • CrCl <10 mL/min, with HD: 300 mg every 7 days. | CrCl <50 mL/min: No data to support use of FDC. Renal dose adjustment should be based on individual components. |

Table 9: Recommended Dose Adjustments for Use of Selected Fixed-Dose Combination Antiretroviral Medications in Patients With Hepatic or Renal Impairment

| FDC | Hepatic Impairment Dose Adjustment [a] | Recommended Dose Adjustments for Renal Impairment | | |
|--|--|---|---|---|
| | | Recommended Dose Adjustment [a] | Individual Components of FDC and Recommended Dose Adjustment [a] | Clinical Comments |
| <i>Protease Inhibitors (PIs)</i> | | | | |
| Darunavir/cobicistat/emtricitabine/tenofovir alafenamide (DRV/COBI/FTC/TAF; Symtuza) [b] See package insert | Child-Pugh A, B: No adjustment is needed. Child-Pugh C: Do not use. | CrCl <30 mL/min: Use of FDC is not recommended. | DRV; DRV/COBI: No renal dose adjustment required unless being combined with TDF. Renal dose adjustment for CrCl <70 mL/min is recommended when combined with TDF. FTC: <ul style="list-style-type: none"> • CrCl 30 to 49 mL/min: 200 mg every 48 hours. • CrCl 15 to 29 mL/min: 200 mg every 72 hours. • CrCl <15 mL/min: 200 mg every 96 hours. TAF: <ul style="list-style-type: none"> • CrCl <15 mL/min, without HD: Use is not recommended. • CrCl <15 mL/min, with HD: No renal dose adjustment is needed. | CrCl <30 mL/min, without HD: No data to support use of FDC. Renal adjustment should be based on individual components. CrCl <30mL/min, with HD: One FDC tablet once daily. On HD days, administer after dialysis [DHHS 2021]. Note: Dose recommended based on data using FTC/TAF as part of FDC with EVG/COBI in patients on HD: In a study of 55 patients on EVG/COBI/FTC/TAF for up to 96 weeks, 18 (33%) had grade 3 or higher ADRs during treatment, and 3 patients discontinued treatment due to adverse effects. The authors concluded that at 48 weeks, the FDC regimen was well tolerated in patients on HD [Eron, et al. 2018]. |
| <i>Nucleoside/Nucleotide Reverse Transcriptase Inhibitors (NRTIs)</i> | | | | |
| Emtricitabine/tenofovir alafenamide (FTC/TAF; Descovy) See package insert | Child-Pugh A, B: No dose adjustment is needed. Child-Pugh C: No data. | CrCl <30 mL/min: Use of FDC is not recommended. | FTC: <ul style="list-style-type: none"> • CrCl 30 to 49 mL/min: 200 mg every 48 hours. • CrCl 15 to 29 mL/min: 200 mg every 72 hours. • CrCl <15 mL/min: 200 mg every 96 hours. TAF: <ul style="list-style-type: none"> • CrCl <15 mL/min, without HD: Use is not recommended. • CrCl <15 mL/min, with HD: No renal dose adjustment is needed. | CrCl <30 mL/min, without HD: No data to support use of FDC. Renal adjustment should be based on individual components. CrCl <30mL/min, with HD: One FDC once daily. On HD days, administer after HD [DHHS 2021]. Note: Dose recommended based on data using FTC/TAF as part of FDC with EVG/COBI in patients on HD: In a study of 55 patients on EVG/COBI/FTC/TAF for up to 96 weeks, 18 (33%) had grade 3 or higher ADRs during treatment, and 3 patients discontinued treatment due to adverse effects. The authors concluded that at 48 weeks, the FDC regimen was well tolerated in patients on HD [Eron, et al. 2018]. |

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|--|---|--|---|---|
| | | Recommended Dose Adjustment [a] | Individual Components of FDC and Recommended Dose Adjustment [a] | Clinical Comments |
| Emtricitabine/tenofovir disoproxil fumarate (FTC/TDF; Truvada) See package insert | Child-Pugh A, B, C: No dose adjustment is needed. | CrCl 30 to 49 mL/min: FTC 200 mg/TDF 300 mg every 48 hours. CrCl <30 mL/min: Use of FDC is not recommended. | FTC: <ul style="list-style-type: none"> • CrCl 30 to 49 mL/min: 200 mg every 48 hours. • CrCl 15 to 29 mL/min: 200 mg every 72 hours. • CrCl <15 mL/min: 200 mg every 96 hours. TDF: <ul style="list-style-type: none"> • CrCl 30 to 49 mL/min: 300 mg every 48 hours. • CrCl 10 to 29 mL/min: 300 mg every 72 to 96 hours. • CrCl <10 mL/min, without HD: No data available. • CrCl <10 mL/min, with HD: 300 mg every 7 days. | CrCl <30 mL/min: No data to support use of FDC. Renal dose adjustment should be based on individual components. |
| Abacavir/lamivudine (ABC/3TC; Epzicom) See package insert | Child-Pugh A, B, C: Do not use. | CrCl <50 mL/min: Use of FDC is not recommended. | ABC: No renal dose adjustment is needed. 3TC: <ul style="list-style-type: none"> • CrCl 30 to 49 mL/min: 150 mg once daily. • CrCl 15 to 29 mL/min: 150 mg first dose, then 100 mg once daily. • CrCl 5 to 14 mL/min: 150 mg first dose, then 50 mg once daily. • CrCl <5 mL/min: 50 mg first dose, then 25 mg once daily. | CrCl >30 mL/min: Limited data to support use of FDC. No elevations in lactate or other ADRs reported in a study of 21 patients with CrCl >30 mL/min who received full dose of 3TC; minimal increases in AUC. [Fischetti, et al. 2018]. CrCl <30 mL/min, without HD: Renal dose adjustment should be based on individual components. 13 patients with CrCl <30 mL/min received 100-150 mg of 3TC with minimal increases in AUC. No elevations in lactate or other ADRs reported [Fischetti, et al. 2018]. CrCl <30 mL/min, with HD: Limited data to support use of FDC. A case series evaluating safety and efficacy of Triumeq (ABC/3TC/DTG) as an FDC in 9 patients with ESRD on HD showed viral suppression was achieved in all 9 patients. No change in immune function. FDC was generally well tolerated; one patient complained of nausea, which resolved without drug discontinuation [Michienzi, et al. 2019]. |

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|-----|--|---|--|---|
| | | Recommended Dose Adjustment [a] | Individual Components of FDC and Recommended Dose Adjustment [a] | Clinical Comments |
| | | | | Note: DTG serum concentrations appear to be reduced in uninfected healthy controls with eGFR <30 mL/min/m ² compared to those with normal kidney function. This may increase the risk of therapeutic failure among patients with HIV drug resistance to INSTIs. [Tivicay package insert]. |

Abbreviations: ADR, adverse drug reaction; AUC, area under the curve; C_{max}, maximum plasma concentration; C_{min}, minimum plasma concentration; CrCl, creatinine clearance; FDC, fixed-dose combination; eGFR, estimated glomerular filtration rate; ESRD, end-stage renal disease; HD, hemodialysis.

Notes:

a. Per package inserts; see links.

b. Per package inserts, FTC can be used at standard dose in FDCs that contain FTC/TAF when CrCl is >30 mL/min. FTC as an individual component requires renal dose adjustment when CrCl is <50 mL/min.

Other ARVs, not included above:

TDF/FTC/RPV (Complera): [See package insert](#)

- Renal dose adjustment: CrCl <50 mL/min: do not use.
- Hepatic dose adjustment: Child-Pugh A, B—no adjustment; Child-Pugh C—no data.

Atazanavir (ATV; Reyataz): [See package insert](#)

- Renal dose adjustment: No adjustment, but use only 300 mg dose with 100 mg RTV; do not use in treatment-experienced patients on HD.
- Hepatic dose adjustment: Child-Pugh A, B—no adjustment; Child-Pugh C—no data.

ATV/COBI (Evotaz): [See package insert](#)

- Renal dose adjustment: Do not use in patients with CrCl <70 mL/min taking a TDF-containing regimen; do not use in treatment-experienced patients on HD.
- Hepatic dose adjustment: No data; not recommended.

Raltegravir (RAL; Isentress): [See package insert](#)

- Renal dose adjustment: None.
- Hepatic dose adjustment: 400 mg twice daily: Child-Pugh A, B—no adjustment; Child-Pugh C—no data. 600 mg once daily: No data; use with caution.

DRUG MANUFACTURER PACKAGE INSERTS

Atripla: FDA. Atripla (efavirenz/emtricitabine/tenofovir disoproxil fumarate) tablets for oral use. 2006. https://www.accessdata.fda.gov/drugsatfda_docs/label/2015/021937s037lbl.pdf [accessed 2020 Mar 5].

Biktarvy: FDA. Biktarvy (bictegravir, emtricitabine, and tenofovir alafenamide) tablets, for oral use. 2018 Feb. https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/210251s000lbl.pdf [accessed 2020 Mar 5].

Complera: FDA. Complera (emtricitabine/rilpivirine/tenofovir disoproxil fumarate) tablets, for oral use. 2013 Jan. https://www.accessdata.fda.gov/drugsatfda_docs/label/2013/202123s003lbl.pdf [accessed 2020 May 14].

- Descovy:** FDA. Descovy (emtricitabine and tenofovir alafenamide) tablets, for oral use. 2016 Apr. https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/208215s000lbl.pdf [accessed 2020 Mar 5].
- Delstrigo:** FDA. Delstrigo (doravirine, lamivudine, and tenofovir disoproxil fumarate) tablets, for oral use. 2018 Aug. https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/210807s000lbl.pdf [accessed 2020 Mar 5].
- Dovato:** FDA. Dovato (dolutegravir and lamivudine) tablets, for oral use. 2019 Apr. https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/211994s000lbl.pdf [accessed 2020 Mar 5].
- Epzicom:** FDA. Epzicom (abacavir sulfate and lamivudine) tablets for oral use. 2012 Mar. https://www.accessdata.fda.gov/drugsatfda_docs/label/2012/021652s015lbl.pdf [accessed 2020 Mar 5].
- Evotaz:** FDA. Evotaz (atazanavir and cobicistat) tablets, for oral use. 2015 Jan. https://www.accessdata.fda.gov/drugsatfda_docs/label/2015/206353s000lbl.pdf [accessed 2020 May 14].
- Genvoya:** FDA. Genvoya (elvitegravir, cobicistat, emtricitabine, and tenofovir alafenamide) tablets, for oral use. 2015 Nov. https://www.accessdata.fda.gov/drugsatfda_docs/label/2015/207561s000lbl.pdf [accessed 2020 Mar 5].
- Isentress:** FDA. Isentress (raltegravir) tablets for oral use. 2013 June. https://www.accessdata.fda.gov/drugsatfda_docs/label/2013/022145s029lbl.pdf [accessed 2020 May 14].
- Juluca:** FDA. Juluca (dolutegravir and rilpivirine) tablets, for oral use. 2017 Nov. https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/210192s000lbl.pdf [accessed 2020 Mar 5].
- Odefsey:** FDA. Odefsey (emtricitabine, rilpivirine, and tenofovir alafenamide) tablets, for oral use. 2016 Mar. https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/208351s000lbl.pdf [accessed 2020 Mar 5].
- Reyataz:** FDA. Reyataz (atazanavir) capsules, for oral use. 2016 Sept. https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/021567s039,206352s004lbl.pdf [accessed 2020 May 14].
- Stribild:** FDA. Stribild (elvitegravir, cobicistat, emtricitabine, tenofovir disoproxil fumarate) tablets, for oral use. 2016 Sep. https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/203100s024lbl.pdf [accessed 2020 Mar 5].
- Symfi Lo:** FDA. Symfi lo (efavirenz, lamivudine, and tenofovir disoproxil fumarate) tablets, for oral use. 2018 Feb. https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/208255s000lbl.pdf [accessed 2020 Mar 5].
- Symtuza:** FDA. Symtuza (darunavir, cobicistat, emtricitabine, and tenofovir alafenamide) tablets, for oral use. 2018 Jul. https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/210455s000lbl.pdf [accessed 2020 Mar 5].
- Triumeq:** FDA. Triumeq (abacavir, dolutegravir, and lamivudine) tablets, for oral use. 2017 Nov. https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/205551s011lbl.pdf [accessed 2020 Mar 5].
- Truvada:** FDA. Truvada (emtricitabine/tenofovir disoproxil fumarate) tablets, for oral use. 2004. https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/021752s047lbl.pdf [accessed 2020 Mar 5].
- Tivicay:** FDA. Tivicay (dolutegravir) tablets, for oral use. 2013. https://www.accessdata.fda.gov/drugsatfda_docs/label/2013/204790lbl.pdf [accessed 2020 Apr 13].

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- Zhang H, Shao Y, Garner W, et al. The effect of hepatic or renal impairment on bicitegravir pharmacokinetics. 18th International Workshop on Clinical Pharmacology of Antiviral Therapy; 2017 Jun 14-17; Chicago, IL. http://www.natap.org/2017/Pharm/Pharm_31.htm