Dosing Guide: Recommended Dose Adjustments for Use of Selected Fixed-Dose Combination Antiretroviral Medications in Patients with Hepatic or Renal Impairment

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		Recommended Dose Adjustments for Renal Impairment		
Fixed-Dose Combination	**Hepatic Impairment Dose Adjustment [a]**	**Recommended Dose Adjustment [a]**	**Individual Components of FDC and Recommended Dose Adjustment [a]**	**Clinical Comments**
Integrase Strand Transfer Inhibitors (INSTIs)				
Abacavir/dolutegravir/ lamivudine (ABC/DTG/3TC; Triumeq) 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. • **DTG:** No renal dose adjustment is needed. • **3TC:** – **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; 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]. • **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 mg to 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. 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]. • **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].
Bictegravir/emtricitabine/ tenofovir alafenamide [b] (BIC/FTC/TAF; Biktarvy)	• **Child-Pugh A, B:** No dose adjustment is needed.	**CrCl <30 mL/min:** Use of FDC is not recommended.	• **BIC:** No renal adjustment is needed. • **FTC:** – **CrCl 30 to 49 mL/min:** 200 mg every 48 hours. – **CrCl 15 to 29 mL/min:** 200 mg every 72 hours.	• **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

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		Recommended Dose Adjustment [a]	Individual Components of FDC and Recommended Dose Adjustment [a]	Clinical Comments
See package insert	• **Child-Pugh C:** Do not use		– **CrCl <15 mL/min:** 200 mg every 96 hours. • **TAF:** – **CrCl <15 mL/min, without HD:** Use is not recommended. – **CrCl <15 mL/min, with HD:** No renal dose adjustment is needed.	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:** – **CrCl 30 to 49 mL/min:** 200mg every 48 hours. – **CrCl 15 to 29 mL/min:** 200 mg every 72 hours. – **CrCl <15 mL/min:** 200mg every 96 hours. • **TDF:** – **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 (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].
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:** – **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:** – **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	• **CrCl <50 mL/min:** Use of FDC is not recommended.	• **DTG:** No renal dose adjustment is needed. • **3TC:** – **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 <50mL/min:** No data to support use of FDC. Renal dose adjustment should be based on individual components.

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		Recommended Dose Adjustment [a]	Individual Components of FDC and Recommended Dose Adjustment [a]	Clinical Comments
	not use.		– **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.	
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.	—	—
Non-Nucleoside Reverse Transcriptase Inhibitor (NNRTIs)				
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:** – **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:** – **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 [AIDSinfo 2019]. • 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:** – **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 < 50 mL/min:** No data to support use of FDC. Renal dose adjustment should be based on individual components.

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Fixed-Dose Combination	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
			• **TDF:** – **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.	
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:** – **CrCl 30 to 49 mL/min:** 150 mg once daily. – **CrCl 15 to 29 mL/min:** 150mg first dose, then 100 mg once daily. – **CrCl 5 to 14 mL/min:** 150 mg first dose, then 50 mg once daily. • **TDF:** – **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:** – **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:** – **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.
Protease Inhibitors (PIs)				
Darunavir/cobicistat/ emtricitabine/tenofovir alafenamide (DRV/COBI/FTC/TAF; Symtuza) [b]	• **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:** – **CrCl 30 to 49 mL/min:** 200 mg every 48 hours.	• **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 [AIDSinfo 2019].

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		Recommended Dose Adjustment [a]	Individual Components of FDC and Recommended Dose Adjustment [a]	Clinical Comments
See package insert			– **CrCl 15 to 29 mL/min:** 200 mg every 72 hours. – **CrCl <15 mL/min:** 200 mg every 96 hours. • **TAF:** – **CrCl <15 mL/min, without HD:** Use is not recommended. – **CrCl <15 mL/min, with HD:** No renal dose adjustment is needed.	• 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].
Nucleoside/Nucleotide Reverse Transcriptase Inhibitors (NRTIs)				
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:** – **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:** – **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 [AIDSinfo 2019]. • 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].
Emtricitabine/tenofovir disoproxil fumarate (FTC/TDF; Truvada) See package insert	• 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:** – **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:** – **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:** – **CrCl 30 to 49 mL/min:** 150 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

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		Recommended Dose Adjustment [a]	Individual Components of FDC and Recommended Dose Adjustment [a]	Clinical Comments
			– **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.	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]. • **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].

Abbreviations: ADR, adverse drug reaction; AUC, area under the curve; C_{max}, maximum plasma concentration; C_{min}, minimum plasma concentration; CrCl, creatinine clearance; 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

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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.				

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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].
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- **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].
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- **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].