

DOSAGE FORM MODIFICATIONS AND RENAL/HEPATIC DOSING OF ANTIRETROVIRALS

Drug Name	Dosage Forms and Color	Adult Dosing in Renal Insufficiency and Hepatic Impairment**	Open Capsule			Crush Tablet			Liquid Form																
			Yes	No	ND*	Yes	No	ND*	Yes	No															
Viread ® (tenofovir, TDF)	300 mg (light blue, almond shaped tablet)	<table style="width: 100%; border: none;"> <tr> <td style="text-align: center;"><u>CrCl</u></td> <td style="text-align: center;"><u>Dose</u></td> <td></td> </tr> <tr> <td>30-49 mL/min</td> <td>300 mg Q48h</td> <td></td> </tr> <tr> <td>10-29 mL/min</td> <td>300 mg twice weekly</td> <td>√1</td> </tr> <tr> <td>ESRD or HD</td> <td>300 mg Q7d</td> <td></td> </tr> </table>	<u>CrCl</u>	<u>Dose</u>		30-49 mL/min	300 mg Q48h		10-29 mL/min	300 mg twice weekly	√1	ESRD or HD	300 mg Q7d								√	√			
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Videx ® (didanosine, ddl)	All Videx EC are white opaque capsules: 125 mg (tan imprint) 200 mg (green imprint) 250 mg (blue imprint) 400 mg (red imprint) Generic delayed-release capsules: 200 mg (green/white), 250 mg (red/white), 400 mg (blue/white) 2, 4 gram bottles (pediatric powder)-- Videx and generic	<table style="width: 100%; border: none;"> <tr> <td style="text-align: center;"><u>CrCl</u></td> <td style="text-align: center;"><u>Dose</u></td> <td style="text-align: center;"><u>Dose</u></td> </tr> <tr> <td></td> <td style="text-align: center;">(>60 kg)</td> <td style="text-align: center;">(<60 kg)</td> </tr> <tr> <td>30-59 mL/min</td> <td>200 mg QD</td> <td>125 mg QD</td> </tr> <tr> <td>10-29 mL/min</td> <td>125 mg QD</td> <td>100 mg QD</td> </tr> <tr> <td><10 mL/min or HD or CAPD</td> <td>125 mg QD</td> <td>75 mg QD</td> </tr> </table>	<u>CrCl</u>	<u>Dose</u>	<u>Dose</u>		(>60 kg)	(<60 kg)	30-59 mL/min	200 mg QD	125 mg QD	10-29 mL/min	125 mg QD	100 mg QD	<10 mL/min or HD or CAPD	125 mg QD	75 mg QD		√		√2,3			√	
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Epivir ® (lamivudine, 3TC)	100 mg (butterscotch, round tablet) 150 mg (white, diamond tablet) 300 mg (gray, modified diamond tablet) 10 mg/ml oral solution (strawberry banana)	<table style="width: 100%; border: none;"> <tr> <td style="text-align: center;"><u>CrCl</u></td> <td style="text-align: center;"><u>Dose</u></td> </tr> <tr> <td>30-49 mL/min</td> <td>150mg QD</td> </tr> <tr> <td>15-29 mL/min</td> <td>150mgx1, then 100mg QD</td> </tr> <tr> <td>5-14 mL/min</td> <td>150mgx1, then 50mg QD</td> </tr> <tr> <td><5 mL/min or HD</td> <td>50mgx1, then 25mg QD</td> </tr> </table>	<u>CrCl</u>	<u>Dose</u>	30-49 mL/min	150mg QD	15-29 mL/min	150mgx1, then 100mg QD	5-14 mL/min	150mgx1, then 50mg QD	<5 mL/min or HD	50mgx1, then 25mg QD					√	√							
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Retrovir ® (zidovudine, AZT)	100 mg (white/blue capsule) 300 mg (white round tablet) 10 mg/ml syrup (strawberry) generic formulations also available in: 100 mg capsule, 300 mg tablets and 50 mg/5 mL syrup	For CrCl<15 mL/min or HD: 100 mg TID			√			√	√																
Ziagen ® (abacavir, ABC)	300 mg (yellow tablet) 20 mg/ml oral solution (strawberry banana)	No dosage adjustment required (300mg PO BID)						√	√																
Combivir ® (AZT/3TC)	300 mg ZDV/150 mg 3TC (white capsule-shaped tablet)	Not recommended in patients with CrCl <50 mL/min						√		√															
Trizivir ® (AZT/3TC/ABC)	300mg ZDV/150mg 3TC/300mg ABC(blue-green capsule-shaped tablet)	Not recommended in patients with CrCl <50 mL/min						√		√															
Epzicom ® (ABC/3TC)	600 mg ABC/300 mg 3TC (orange capsule-shaped tablet)	Not recommended in patients with CrCl <50 mL/min						√		√															
Truvada ® (FTC/TDF)	300 mg TDF + 200 mg FTC (blue, capsule-shaped tablet)	For CrCl=30-49 mL/min, dose 1tablet Q48h Not recommended in patients with CrCl <30 mL/min						√		√															
Atripla ® (EFV/FTC/TDF)	600mg EFV+ 200mg FTC+ 300mg TDF (pink, capsule-shaped tablet)	Not recommended in patients with CrCl <50 mL/min						√4		√															
Sustiva ® (efavirenz, EFV)	50 mg (gold/white capsule) 100 mg (white capsule) 200 mg (gold capsule) 600 mg (yellow, capsule-shaped tab)	No dosage adjustment (600mg QD). Use with caution in hepatic impairment.			√5				√6																
Viramune ® (nevirapine, NVP)	200 mg (white, oval tablets) 50 mg/ 5 ml suspension	No dosage adjustment (200mg BID). Avoid use in moderate to severe hepatic impairment.					√		√																
Rescriptor ® (delavirdine, DLV)	100mg (white, capsule-shaped tablet) 200mg (white, capsule-shaped tablet)	No dosage adjustment (400mg TID). Use with caution in hepatic impairment.					√7			√															

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			Yes	No	ND*	Yes	No	ND*	Yes	No
Reyataz ® (atazanavir, ATV)	100 mg (blue/white capsule)	<u>Child-Pugh Score</u>								
	150 mg (blue/powder blue capsule)	<u>Dose</u> 7-9 300mg QD			√8					√
	200 mg (blue capsule)	>9 not recommended								
Norvir ® (ritonavir, RTV) 13	100 mg (white capsule)	No dosage adjustment in mild hepatic impairment; no data for moderate to severe (use with caution).		√					√9	
	80 mg/ml oral solution (caramel/peppermint)									
Agenerase ® (amprenavir, APV)	50 mg (cream oblong tablet)	<u>Child-Pugh Score</u>								
	15 mg/ml oral solution (grape/bubblegum/peppermint)	<u>Dose</u> 5-8 450mg BID		√						√
		9-12 300mg BID								
Lexiva ® (fosamprenavir, f-APV)	700 mg (pink capsule-shaped tablet)	<u>Child-Pugh Score</u>								
		<u>Dose</u> 5-8 700mg BID					√			√
		9-12 not recommended								
Kaletra ® (LPV/RTV)	1 tablet (yellow) =200 mg LPV + 50 mg RTV	No dosage recommendation; use with caution in hepatic impairment.		√					√14	
	80mg LPV+20mg RTV/mL oral solution (cotton candy/menthol/vanilla)									
Prezista ® (darunavir,)	300 mg (orange tablet)	No dosage recommendation; use with caution in hepatic impairment. No need for renal adjustment.				√1				√*
Aptivus ® (tipranavir, TPV)	250 mg (pink oblong capsule)	No dosage recommendations in moderate hepatic insufficiency. Contraindicated in moderate to severe hepatic insufficiency.			√14			√		√
Viracept ® (nelfinavir, NFV)	250 mg (blue capsule-shaped tablet)	No dosage recommendation; use with caution in hepatic impairment.				√10				√
	625 mg (white oval-shaped tablet)									
	50 mg/g powder									
Crixivan ® (indinavir, IDV)	All are semi-translucent white capsules	For mild to moderate hepatic insufficiency due to cirrhosis: 600mg q8h								
	100 mg (green imprint)				√11					√
	200 mg (blue imprint)									
	333 mg (red imprint)									
	400 mg (green imprint)									
Invirase ® (saquinavir, SQV)	200 mg (brown/green capsule)	No dosage recommendation; use with caution in hepatic impairment			√					√
	500 mg (orange/gray oval tablets)									
Fuzeon ® (enfuvirtide, EFV)	Single-use vials for injection reconstituted to 90 mg/ml	No dosage adjustment in renal insufficiency (no info on CrCl<35 mL/min) and no recommendation in hepatic impairment								

- No data available; however powder is water-soluble and not enteric-coated or extended-release.
- XR or EC capsules should not be opened.
- Can chew tablet or mix with at least 1 ounce of water and stir to dissolve before swallowing. Can add 2 tbsp of apple juice for flavor and drink right away.
- Tablets are not XR or EC thus crushing or breaking tablets is possible, however it is not recommended as efavirenz is insoluble in water and there are no studies regarding this use per correspondence with BMS/Gilead
- No data available. Can mix contents of three 200-mg capsules with at least 5 ml of MCT Oil (Captex® 300) or 15 ml of Orasweet®, just prior to administration. Grind powder in mortar to provide fine powder in suspension. A has been described when EFV was mixed with applesauce; therefore grape jelly has been used to disguise the peppery taste.
- Pediatric Oral Liquid Expanded Access Program for HIV-infected children and adolescents ages 3-16 years (call 1-877-372-7097).
- 100mg tablets may be mixed in water. Add four 100mg tabs to 3 oz of water, allow to stand for few minutes, stir, and consume promptly. Rinse glass and swallow remaining fluid. 200mg tabs should be taken as intact tabs readily disperse in water.
- In person unable to swallow can open and add two 200-mg capsules in 4oz of applesauce just prior to administration.
- Can mix with Ensure®, Advera®, or chocolate milk. Can flush feeding tube with these liquids.
- Can be dissolved in small amount of water. Need to rinse and swallow remaining liquid. RTV can precipitate with other aqueous solutions.
- No data available. Preliminary studies have shown that it is stable for hours after mixing with fruit purees (banana, pear, and apple).
- Oral solution not recommended in patients with renal or hepatic failure.
- DHHS HIV treatment guidelines do not recommend full-dose RTV as the sole PI in an ARV regimen for initial therapy due to poor tolerability.
- Kaletra oral solution and TPV capsules contain alcohol.

* ND: no data available

** No dosage recommendations with use of NRTIs in hepatic impairment and no dosage adjustments necessary with use of PIs and NNRTIs in renal insufficiency.

Parya Saberi, Pharm.D. and Cristina Gruta, Pharm.D.
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