Darunavir (DRV) and Ritonavir (RTV)

Formulations available:

Darunavir:

- Tablets: 75 mg, 150 mg, 400 mg, 600 mg (if not able to swallow whole, may be crushed or chewed)
- [Oral suspension: 100 mg/ml (Not yet registered in SA, available on compassionate use access from manufacturer with SAHPRA Sec 21 approval)]

Ritonavir:

- Oral powder: 100 mg/packet (each 100 mg packet of RTV powder should be mixed with a small amount of water if administering the whole packet (100 mg), or 10 ml water if not administering the whole packet and administer the appropriate dose as per Table below or soft food and immediately ingested)
- Tablets: 100 mg (must be swallowed whole, not crushed or divided or chewed)

Dosing:

Children <3 years of age OR <10 kg: DRV is not recommended

Weight	No darunavir resistance-associated	Darunavir resistance-associated
band	mutations on genotyping	mutations on genotyping
(kg)		(V11I, V32I, L33F, I47V, I50V, I54M, I54L,
		T74P, L76V, I84V, L89V)
	Dose of darunavir (35 mg/kg,	Dose of darunavir (20 mg/kg, maximum
	maximum 800 mg) and ritonavir (7	600 mg) and ritonavir (3 mg/kg,
	mg/kg, maximum 100 mg):	maximum 100 mg):
	once daily with food	twice daily with food
10 - <12	DRV 375 mg (2 x 150 mg + 1 x 75 mg	DRV 225 mg (3 x 75 mg tablets), + RTV oral
	tablets) + RTV oral powder 100 mg (1	powder 100 mg (1 packet) in 10 ml water
	packet) in 10 ml water & administer	& administer 4 ml (40 mg)
	8 ml (80 mg)	
12 - <13	DRV 450 mg (3 x 150 mg tablets) +	DRV 225 mg (3 x 75 mg tablets), + RTV oral
	RTV oral powder 100 mg (1 packet)	powder 100 mg (1 packet) in 10 ml water
	in 10 ml water & administer 10 ml	& administer 4 ml (40 mg)
	(100 mg)	
13 - <14	DRV 450 mg (3 x 150 mg tablets) +	DRV 300 mg (2 x 150 mg tablets), + RTV
	RTV oral powder 100 mg (1 packet)	oral powder 100 mg (1 packet) in 10 ml
	in 10 ml water & administer 10 ml	water & administer 5 ml (50 mg)
	(100 mg)	
14 - <15	DRV 525 mg (3 x 150 mg tablets + 1 x	DRV 300 mg (2 x 150 mg tablets), + RTV
	75 mg tablet) + RTV oral powder 100	oral powder 100 mg (1 packet) in 10 ml
	mg (1 packet) in 10 ml water &	water & administer 5 ml (50 mg)
	administer 10 ml (100 mg)	
15 - <30	DRV 600 mg + RTV 100 mg (1 packet)	DRV 400 mg (1 x 400 mg tablet) + RTV oral
	or 100 mg tablet if able to swallow	powder 100 mg (1 packet) or 100 mg
	whole	tablet if able to swallow whole
30 - <40	DRV 675 mg (1 x 600 mg tablet + 1 x	DRV 475 mg (1 x 400 mg + 1 x 75 mg
	75 mg tablet) + RTV 100 mg (1	tablets) + RTV 100 mg (1 packet) or 100
	packet) or 100 mg tablet if able to	mg tablet if able to swallow whole
	swallow whole	
≥40	DRV 800 mg (2 x 400 mg tablets) +	DRV 600 mg (1 x 600 mg tablet) + RTV 100
	RTV 100 mg (1 packet) or 100 mg	mg (1 packet) or 100 mg tablet if able to
	tablet if able to swallow whole	swallow whole

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Adapted from US FDA prescribing information:Darunavir [package insert]. Food and Drug Administration. 2016. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/021976s043,202895s017lbledt.pdf.

<u>Children on concomitant rifampicin-containing TB regimens:</u>

 DRV is not compatible with these regimens, and the clinician should engage with the 3rd line committee to review ART and TB treatment