

3.2 LOPINAVIR/RITONAVIR (LPV/r) (CO-FORMULATION)

FORMULATIONS

Co-formulated heat-stable tablets	Capsules	Liquid	FDC
Paediatric LPV 100 mg/RTV 25 mg Adult LPV 200 mg/RTV 50 mg	None	LPV 80 mg/ml + RTV 20 mg/ml	None

DOSE AND FREQUENCY OF DOSING

LPV target dose

- 230 – 350 mg/m² twice daily

Maximum dose

- LPV 400 mg + RTV 100 mg twice daily

Administration – tablets

- Must be administered intact and cannot be split or crushed

Administration – liquid

- Must be well shaken

Storage

- Liquid should be refrigerated.
- Can be stored at room temperature (up to 25°C) for two months (at >25°C the drug degrades more rapidly).
- For tablets, exposure to high humidity is not recommended for more than 2 weeks.

OTHER COMMENTS

General

- Higher doses of LPV/r may be required when co-administered with enzyme-inducing drugs such as NVP, EFV, FPV, rifampicin.
- No food restrictions although bioavailability is reportedly increased when administered with food
- Should be taken with food
- In non-fasting state, absolute bioavailability of LPV/r liquid is decreased by 22% compared with LPV/r tablet.
- Low volume but bitter taste
- Once-daily dosing is not approved for infants or children.
- LPV/r liquid has a high alcohol content.

Pharmacokinetic data

- Available for 14 days and older

Major drug interactions

- Not recommended to be taken with rifampicin, omeprazole or simvastatin

Ref: <http://www.rxabbott.com/pdf/kaletratapi.pdf>
http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?fuseaction=Search.Label__ApprovalHistory
<http://www.who.int/hiv/pub/paediatric/antiretroviral/en/index.html>

LOPINAVIR/RITONAVIR
Recommended dosing based on weight-bands for children >6 weeks using liquid

Weight range (kg)		Target dose 230 – 350 mg/m ² twice daily		Dose (ml)	
Bottom	Top	Formulation		a.m.	p.m.
3	3.9	80 mg LPV/20 mg RTV	ml liquid	1 ml	1 ml
4	4.9	80 mg LPV/20 mg RTV	ml liquid	1.5 ml	1.5 ml
5	5.9	80 mg LPV/20 mg RTV	ml liquid	1.5 ml	1.5 ml
6	6.9	80 mg LPV/20 mg RTV	ml liquid	1.5 ml	1.5 ml
7	7.9	80 mg LPV/20 mg RTV	ml liquid	1.5 ml	1.5 ml
8	8.9	80 mg LPV/20 mg RTV	ml liquid	1.5 ml	1.5 ml
9	9.9	80 mg LPV/20 mg RTV	ml liquid	1.5 ml	1.5 ml
10	10.9	80 mg LPV/20 mg RTV	ml liquid	2 ml	2 ml
11	11.9	80 mg LPV/20 mg RTV	ml liquid	2 ml	2 ml
12	13.9	80 mg LPV/20 mg RTV	ml liquid	2 ml	2 ml
14	16.9	80 mg LPV/20 mg RTV	ml liquid	2.5 ml	2.5 ml
17	19.9	80 mg LPV/20 mg RTV	ml liquid	2.5 ml	2.5 ml
20	24.9	80 mg LPV/20 mg RTV	ml liquid	3 ml	3 ml
25	29.9	80 mg LPV/20 mg RTV	ml liquid	3.5 ml	3.5 ml
30	34.9	80 mg LPV/20 mg RTV	ml liquid	4 ml	4 ml

LOPINAVIR/RITONAVIR

Recommended dosing based on weight-bands for children >6 weeks using paediatric tablets

Weight range (kg)		Target dose 230 – 350 mg/m ² twice daily		Dose (tablets)	
Bottom	Top	Formulation		a.m.	p.m.
3	3.9	100 mg LPV/25 mg RTV	tablet	NR	NR
4	4.9	100 mg LPV/25 mg RTV	tablet	NR	NR
5	5.9	100 mg LPV/25 mg RTV	tablet	NR	NR
6	6.9	100 mg LPV/25 mg RTV	tablet	NR	NR
7	7.9	100 mg LPV/25 mg RTV	tablet	NR	NR
8	8.9	100 mg LPV/25 mg RTV	tablet	NR	NR
9	9.9	100 mg LPV/25 mg RTV	tablet	NR	NR
10	10.9	100 mg LPV/25 mg RTV	tablet	2	1
11	11.9	100 mg LPV/25 mg RTV	tablet	2	1
12	13.9	100 mg LPV/25 mg RTV	tablet	2	1
14	16.9	100 mg LPV/25 mg RTV	tablet	2	2
17	19.9	100 mg LPV/25 mg RTV	tablet	2	2
20	24.9	100 mg LPV/25 mg RTV	tablet	2	2
25	29.9	100 mg LPV/25 mg RTV	tablet	3	3
30	34.9	100 mg LPV/25 mg RTV	tablet	3	3

Note: Children 14 – 24.9 kg can be dosed with adult tabs (200 mg LPV/50 mg RTV), 1 tab am and 1 tab pm.

Children 25 – 34.9 kg can be dosed with adult tabs (200 mg LPV/50 mg RTV), 2 tabs am and 1 tab pm.