

The November 2007 changes to the Kaletra label include clear instructions regarding the importance of accurate calculation of the dose of Kaletra to minimize the risk for medication errors and overdose or under dose, and the addition of tablet dosing to section 2.2 *Pediatric Patients* as follows.

Table 1. Dosing Recommendations for Pediatric Patients for KALETRA <u>Without</u> Concomitant Nevirapine, Efavirenz, or (Fos)amprenavir			
Weight (kg)	Dose based on lopinavir component *	Volume of Oral Solution twice-daily (80 mg lopinavir/20 mg ritonavir per mL)	Number of 100/25 mg Tablets twice-daily
7 to < 15 kg	12 mg/kg BID†		
7 to 10 kg		1.25 mL	Tablets are not recommended. Use oral solution
> 10 to < 15 kg		1.75 mL	Tablets are not recommended. Use oral solution
15 to 40 kg	10 mg/kg BID†		
15 to 20 kg		2.25 mL	2#
> 20 to 25 kg		2.75 mL	2#
> 25 to 30 kg		3.5 mL	3
> 30 to 35 kg		4 mL	3
> 35 to 40 kg		4.75 mL	4 (or two 200/50 mg tablets)
> 40 kg	400 mg BID	5 mL	4 (or two 200/50 mg tablets)
<p>* Dosing based on the lopinavir component of lopinavir/ritonavir solution (80 mg/20 mg per mL).</p> <p>† Dose is also approximately equivalent to lopinavir/ritonavir 230/57.5 mg/m<sup>2</sup>.</p> <p># Alternatively one 200/50 mg tablet may be used for this dose in those patients who can swallow the larger tablet</p>			

Table 2. Dosing Recommendations for Pediatric Patients for KALETRA With Concomitant Neviraprine, Efavirenz, or (Fos)amprenavir

Weight (kg)	Dose based on lopinavir component*	Volume of Oral Solution twice-daily (80 mg lopinavir/20 mg ritonavir per mL)	Number of 100/25 mg Tablets twice-daily
7 to < 15 kg	13 mg/kg BID†		
7 to 10 kg		1.5 mL	Tablets are not recommended. Use oral solution
> 10 to < 15 kg		2 mL	Tablets are not recommended. Use oral solution
15 to 45 kg	11 mg/kg BID†		
15 to 20 kg		2.5 mL	2#
> 20 to 25 kg		3.25 mL	3
> 25 to 30 kg		4 mL	3
> 30 to 35 kg		4.5 mL	4 (or two 200/50 mg tablets)
> 35 to 40 kg		5 mL	4 (or two 200/50 mg tablets)
> 40 to 45 kg		5.75 mL	4 (or two 200/50 mg tablets)
> 45 kg	533 mg BID for oral solution use  400 mg or 600 mg BID for Tablet use	6.5 mL	4 (or two 200/50 mg tablets) or 6 (or three 200/50 mg tablets)  [See DOSAGE AND ADMINISTRATION (2.1)]

\* Dosing based on the lopinavir component of lopinavir/ritonavir solution (80 mg/20 mg per mL).

† Dose is also approximately equivalent to lopinavir/ritonavir 300/75 mg/m<sup>2</sup>.

# Alternatively one 200/50 mg tablet may be used for this dose in those patients who can swallow the larger tablet