



August 6, 2007

Direct Healthcare Professional Communication on Kaletra® (lopinavir/ritonavir) oral solution and accidental overdose in children

Dear Healthcare Professional,

Summary

Abbott was recently notified of an accidental overdose when an infant received a significantly large dose of Kaletra (lopinavir/ritonavir) Oral Solution. The infant subsequently died.

Abbott is reminding you that:

- Kaletra Oral Solution is highly concentrated, containing 80 mg lopinavir and 20 mg **ritonavir** per mL (not per bottle).
- Children dosages are calculated **based** on body weight. A child should receive **less** than 5 mL oral solution per dose unless they are also receiving certain concomitant **antiretroviral** medicines. Reference should be made to the attached prescribing information.

Further information on the safety concern

- The accidental overdose occurred in a **44-day-old** infant, born at **30 weeks gestation with HIV**, who was given approximately **6.5 mL of Kaletra Oral Solution** (this is about **10 times** the calculated volume). The infant died nine days later of **cardiogenic shock**.
- Special attention must be paid to accurate calculation of the dose, transcription of the medication **order**, dispensing information and dosing instructions to minimize the risk for medication errors. Reference should be made to the attached **local** prescribing information for dosing recommendations in children.

Please see accompanying **full** prescribing information



Dosing guidelines for children receiving the **recommended** dose of **lopinavir/ritonavir** using **Kaletra** Oral Solution

Weight (kg)	Dose (mg/kg)*	Volume of Oral Solution B.I.D. (80 mg lopinavir/20 mg ritonavir per mL)
7 to less than 15 kg	12 mg/kg B.I.D.	
7 to 10 kg		1.25 mL
greater than 10 to less than 15 kg		1.75 mL
15 to 40 kg	10 mg/kg B.I.D.	
15 to 20 kg		2.25 mL
greater than 20 to 25 kg		2.75 mL
greater than 25 to 30 kg		3.50 mL
greater than 30 to 35 kg		4.00 mL
greater than 35 to 40 kg		4.75 mL
greater than 40 kg	Adult Dose	5.0 mL
*Dosing based on the lopinavir component of lopinavir/ritonavir solution (80 mg/20 mg per mL). Note: Use adult dosage recommendation for children greater than 12 years of age.		

- Abbott requests you to make patients, caretakers and your staff aware of the need for care when administering **Kaletra** Oral Solution in children.

Call for reporting

Please report adverse reactions in **accordance** with your local reporting requirements. You may report an adverse event to Abbott **Pharmacovigilance** at 1-800-633-9110.

Communication information

If you have any questions or need additional **information** about the **Kaletra** Oral Solution, please **contact** Abbott Global Medical Information at 1-800-633-9110.

Sincerely,

Robert **Hoff**, MD
Senior Medical Director
Global **Medical Communications**

Please see accompanying full prescribing information



Please see the attached local prescribing information for Indications and Safety information.

Annexes:

■ .KALETRA Oral Solution Prescribing Information