Abbott Laboratories Ireland Ltd.,
4051 Kingswood Drive,
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Telephone: 01 469 1500
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3 August 2007

IMPORTANT SAFETY INFORMATION

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

The content of this letter has been agreed with the European Authorities, including the Irish Medicines Board.

Summary

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

Abbott is reminding you that:

- Kaletra oral solution is **contraindicated** for use in children under the age of two,
- 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 surface area (BSA). A child should receive **less** than 5 ml oral solution per dose, unless they are receiving concomitant nevirapine or efavirenz.

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 Summary of Product Characteristics for dosing recommendations in children.

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Dosing guidelines for children receiving the recommended dose of lopinavir/ritonavir using Kaletra Oral Solution as provided in the current Summary of Product Characteristics:

Body Surface Area* (m^2)	Twice daily oral solution dose
0.25	0.7 ml
0.40	1.2 ml
0.50	1.4 ml
0.75	2.2 ml
0.80	2.3 ml
1.00	2.9 ml
1.25	3.6 ml
1.3	3.7 ml
1.4	4.0 ml
1.5	4.3 ml
1.75	5 ml

* Body surface area can be calculated with the following equation

BSA (m^2) = $\sqrt{}$ (Height (cm) X Weight (kg) / 3600)

- Abbott requests you to make patients, caregivers 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 the Medical Department, Abbott Laboratories Ireland Limited, 4051 Kingswood Drive, Citywest Business Campus, Dublin 24, telephone: 01-4691500 or to the Irish Medicines Board in the usual way.

Communication information

If you have any questions or need additional information about Kaletra oral solution, please contact the Medical Department, Abbott Laboratories Ireland Limited, 4051 Kingswood Drive, Citywest Business Campus, Dublin 24, telephone: 01-4691500.

Sincerely,

Francois Boer, M.D.
Interim Medical Director
Abbott Ireland

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