

10<sup>th</sup> February 2014

## **TRIOMEL – Reduction of maximum hourly infusion rate for children aged 2 to 11 years**

Dear Healthcare Professional,

Baxter Healthcare Limited, in agreement with the Irish Medicines Board (IMB), would like to inform you of the following:

### **Summary**

- The maximum hourly infusion rate of lipid in the product information of TRIOMEL should be revised for children aged 2-11 years to match the recommendations in the 2005 European Society for Paediatric Gastroenterology, Hepatology & Nutrition / European Society for Parenteral and Enteral Nutrition (ESPGHAN/ESPEN) Guidelines<sup>[1]</sup> for this age group.
- **These guidelines recommend a maximum lipid infusion rate of 0.13 g/kg/hour for children aged 2-11 years.**
- **As a result, the maximum infusion rates for fluids, amino acids and glucose in the TRIOMEL range will also be updated** in the Summary of Product Characteristics (SmPC) and Patient Information Leaflet (PIL). Please see dosing regimen table below for full information.

### **Further information**

TRIOMEL are a range of products indicated for parenteral nutrition (PN) for adults and children greater than 2 years of age when oral or enteral nutrition is impossible, insufficient or contraindicated.

These products provide a 3-in-1 total parenteral nutrition (TPN) solution that contains macronutrients (lipids, amino acids and glucose); certain TRIOMEL formulations also include electrolytes.

The product information for TRIOMEL currently recommends a maximum hourly infusion rate for lipids for children 2-11 years which is higher than that stated in the 2005 ESPGHAN/ESPEN Guidelines for this age group. An increased lipid infusion rate may increase the risk of adverse reactions (e.g., fat overload syndrome, septicemia, or hypertriglyceridemia). No adverse reactions have been received by Baxter related to this issue since marketing.

In this age group, the limiting factor for the maximum infusion rate for each product is limited by the maximum infusion rate of the lipid. As a result, the maximum infusion rates for fluids, amino acids and glucose stated in the product information are also being revised.

The revised dosing table is shown below.

**Table: Revised maximum hourly infusion rate of TRIOMEL for children 2-11 years old**

Constituent	Maximum Recommended infusion rate <sup>a</sup>	TRIOMEL PERIPHERAL 4 g/l nitrogen 700 kcal/l with electrolytes	TRIOMEL 5 g/l nitrogen 990 kcal/l with electrolytes	TRIOMEL 7 g/l nitrogen 1140 kcal/l with electrolytes	TRIOMEL 7 g/l nitrogen 1140 kcal/l	TRIOMEL 9 g/l nitrogen 1070 kcal/l with electrolytes	TRIOMEL 9 g/l nitrogen 1070 kcal/l
Fluids (ml/kg/h)		4.3	3.3	3.3	3.3	3.3	3.3
Amino acids (g/kg/h)	0.20	0.11	0.11	0.15	0.15	0.19	0.19
Glucose (g/kg/h)	1.2	0.32	0.38	0.46	0.46	0.36	0.36
Lipids (g/kg/h)	<b>0.13</b>	<i>0.13</i>	<i>0.13</i>	<i>0.13</i>	<i>0.13</i>	<i>0.13</i>	<i>0.13</i>
<i>Italics: limiting factor</i>							
a: Recommended values from 2005 ESPEN-ESPGHAN Guidelines							

**Call for reporting**

Please contact your local Baxter representative if you have any further queries.

Please report suspected adverse reactions with the use of TRIOMEL to the IMB, preferably through the online reporting option at [www.imb.ie](http://www.imb.ie), or alternatively via the downloadable or Yellow Card report forms. Adverse reactions can also be reported to the IMB by calling on (01) 676 4971.

Any suspected adverse reactions observed during use may also be reported to Baxter Healthcare directly by calling 01-206-5500 or by email to [qa\\_dublin@baxter.com](mailto:qa_dublin@baxter.com).

Sincerely,



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[1] Koletzko, B., Goulet, O., Hunt, J., Krohn, K., Shamir, R., Parenteral Nutrition Guidelines Working Group, et al. *Guidelines on Paediatric Parenteral Nutrition of the European Society of Paediatric Gastroenterology, Hepatology and Nutrition (ESPGHAN) and the European Society for Clinical Nutrition and Metabolism (ESPEN)*, Journal of Pediatric Gastroenterology and Nutrition. 2005 Nov; 41 Suppl 2:S1-87.