27.09.2013

Numeta G16%E – potential risk of hypermagnesaemia

Dear Healthcare Professional,

Baxter Healthcare, in agreement with the European Medicines Agency and the Medicines Authority, would like to inform you of the following:

Summary

- There is a potential risk for hypermagnesaemia when Numeta G16%E is administered to term newborn infants and children up to 2 years, particularly:
  - In patients with reduced renal function, and
  - newborn infants of mothers who were receiving supplemental magnesium prior to delivery.

Healthcare professionals are advised of the following:

- Serum magnesium levels should be monitored, along with other electrolyte levels at baseline and at appropriate intervals thereafter, in accordance with routine clinical practice and the clinical needs of the individual patient.

- Healthcare professionals should be vigilant for signs of hypermagnesaemia such as generalized weakness, respiratory failure, hypotension, arrhythmias (especially if not otherwise explained by the clinical condition of the infant/child). Hypermagnesaemia may also cause non-specific symptoms such as nausea, vomiting and flushing. It should be noted that clinical signs may not be identifiable unless hypermagnesaemia is severe.

- If serum magnesium levels are elevated or signs of hypermagnesaemia are identified, the infusion of Numeta G16%E should be stopped or infusion rate reduced and alternative fluids, nutrition and electrolytes prescribed as deemed clinically appropriate.

Further information and recommendations

Background

An evaluation of the benefits and risks of Numeta G13%E and Numeta G16%E has been conducted after reports of hypermagnesaemia in preterm neonates administered Numeta G13%E.

This evaluation has resulted in the conclusion that the benefits exceed the risks for Numeta G16%E, provided the product information is updated with advice and warnings as summarized above. In addition, Baxter will undertake a study to further evaluate

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magnesium levels observed in term newborn infants and children up to two years of age treated with Numeta G16%E in routine clinical practice.

Numeta G16%E provides approximately 0.3 mmol/kg/day of magnesium, when administered at the maximum recommended daily dose of 96ml/kg/day. This is slightly higher than recommended in international guidelines (1) for the indicated age groups i.e. term newborn infants and children up to 2 years of age.

The corresponding serum levels of magnesium following administration of a maximum daily dose of Numeta G16%E is unknown. Impaired renal function may affect the ability to excrete magnesium. Thus, the risk for hypermagnesaemia may be increased in a patient with reduced renal function.

As of today, one case of hypermagnesaemia without clinical symptoms or signs has been reported with Numeta G16%E in an infant. The infant also received additional magnesium, and when this source was withdrawn, the magnesium levels returned to within normal range.

Numeta G13%E provides higher levels of magnesium than recommended in available guidelines for preterm newborn infants and there have been reports of hypermagnesaemia associated with the use of the product in preterm newborn infants. Therefore Numeta G13%E has been suspended until the product can be reformulated with an acceptable magnesium concentration.

(1) *the European Society of Parenteral and Enteral Nutrition (ESPEN), European Society for Paediatric Gastroenterology, Hepatology and Nutrition (ESPGHAN) and the American Society of Parenteral and Enteral Nutrition (ASPEN)*

Call for reporting

Please report any suspected adverse reactions to any medicine to the Medicines Authority through:

ADR Reporting
The Medicines Authority
Post-Licensing Directorate
203 Level 3, Rue D'Argens
GŻR-1368 Gżira
Website: www.medicinesauthority.gov.mt
e-mail: postlicensing.medicinesauthority@gov.mt

Any suspected adverse reactions observed during use of Numeta may also be reported to Baxter's Malta representative:
Drugsales Ltd, Russell Buildings
Naxxar Road, Lija, IKL 9022, Malta
Tel: +356 21 419 070/1/2
Fax: +356 21 438 260
Email: safety@drugsalesltd.com

Should you have any question, do not hesitate to contact Drugsales Ltd on telephone number +356 21 419 070/1/2 or via email on safety@drugsalesltd.com

Sincerely,

Adrian Busuttil B.Pharm (Hons)

Responsible Person / Regulatory Affairs officer

Drugsales Ltd