24.06.2013

Hypermagnesaemia associated with Numeta G13%E

Dear Healthcare Professional,

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

Summary

- Cases of hypermagnesaemia have been reported in premature infants administered Numeta G13%E 300 ml
- While the issue is further investigated, a voluntary recall Numeta G13%E from the market is planned since our preliminary investigation suggest that the product provides higher levels of magnesium than recommended in available guidelines for preterm newborn infants
- Numeta G13% should not be used unless there is no other alternative available. In such situations, Baxter Healthcare can provide Numeta G13%E. In case of use of Numeta G13%E, the following should be taken into account
    a. Be vigilant of signs of hypermagnesaemia such as generalized weakness, respiratory failure, hypotension, arrhythmias (especially if not otherwise explained by the clinical condition of the neonate).
    b. Serum magnesium levels are recommended to be closely monitored
    c. If serum magnesium levels are elevated (above reference range normal values) the infusion rate of Numeta G13%E should be stopped or reduced as deemed clinically appropriate and safe.

Further information on the safety concern and the recommendations

Between March and May 2013, Baxter Healthcare has received thirteen (13) adverse event reports of hypermagnesaemia in premature infants administered with Numeta G13%E.

Clinical signs of hypermagnesaemia can include generalized weakness, respiratory failure, hypotension, arrhythmias (especially if not otherwise explained by the clinical condition of the neonate). Many of these signs can be present in preterm infants because of their early birth status and immature organ function. Therefore, it may be difficult to discern effects of hypermagnesaemia from common clinical signs seen in the preterm infant.

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Based on our preliminary investigation, Numeta G13%E provides higher levels of magnesium than given in available guidelines for preterm newborn infants. The content is in accordance with the product specification, i.e. this finding is not due to a quality defect.

Baxter is planning to voluntarily recall Numeta G13%E from the market to prevent risk of hypermagnesaemia in preterm newborn infants.

Baxter recognizes that there might be exceptional situations where no alternative product to Numeta G13%E for the feeding of premature neonates exists. In such situations, the use of Numeta G13%E could be considered if treatment is carefully monitored.

There are two other formulations of Numeta; Numeta G16%E (500 ml) for patients aged 0-2 years old and Numeta G19%E (1000 ml) for patients aged 2-18 years old. Also these formulations contain magnesium. No case reports describing hypermagnesaemia have been reported for these two formulations. However, it is recommended to be vigilant to potential signs of hypermagnesaemia also in these patient groups.

In Malta only the Numeta 16%E formulation is currently being marketed. This formulation will remain available pending the outcome of the EU-wide review.

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: abusuttil@drugsalesltd.com or giulia@drugsalesltd.com

Should you have any question, do not hesitate to contact Drugsales Ltd.

Yours sincerely

Dr Iain McNeil
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