Review of Numeta G13%E and G16%E started

20.07.2013 | Circular Number P17/2013

Information on Medicinal Product

Numeta are intravenous (into a vien) nutrition preparations are given into a vein to provide nutritional support in children who cannot be fed any other way. They contain nutrients such as glucose (sugar), lipids (fats), aminoacids and other important substances including magnesium. Numeta G13%E is used in premature newborns while Numeta G16%E is used in full-term newborns and children up to 2 years. Both Numeta G13%E and Numeta G16%E are authorised for use on Malta but only the G16%E is currently in use at Mater-Dei hospital.

Information from European Medicines Agency about the safety concern

The European Medicines Agency has started a review of Numeta G13%E and Numeta G16%E following reports of hypermagnesaemia (high blood levels of magnesium) in premature babies. Reports of hypermagnesaemia were received in premature babies taking Numeta G13%E. Although no reports were received for Numeta G16%E, Numeta G16%E is being included in the EMA review because it also contains magnesium and is used in newborn babies and very young children who may be at risk of developing hypermagnesaemia.

The EMA will assess this safety concern and its impact on the benefit-risk balance of Numeta G13%E and Numeta G16%E, and will issue an opinion on whether the product can be used safely following adequate risk minimisation measures.

In Malta

For Healthcare Professionals

The marketing authorisation holder started a voluntary recall of Numeta G13%E from European countries where it is marketed and to re-formulate it to reduce its magnesium content. Numeta G13%E will remain on the market in situations where no suitable alternative is available. The G16%E will remain on the market but doctors healthcare professionals should be vigilant for symptoms of hypermagnesaemia such as weakness, breathing problems, hypotension (low blood pressure) and heart problems. In addition, doctors

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should closely monitor magnesium blood levels and stop Numeta G16%E or reduce the rate of infusion if magnesium levels are high. The marketing authorisation holder 's local representatives have already issued a letter to the concerned healthcare professionals to this effect.

The European Medicines Agency is inviting all stakeholders (e.g. healthcare professionals, patients' organisations, the general public) to submit data relevant to this procedure. Please visit www.ema.europa.eu should you need more details.

Reporting Adverse Drug Reactions

Healthcare professionals and patients are encouraged to maintain vigilance on Numeta G16%E. Suspected Adverse Drug Reactions (side effects) may be reported using the Medicines Authority yellow card scheme or online at **http://www.medicinesauthority.gov.mt/adrportal** or to the marketing authorisation holder or their local representatives.

Dr John J Borg PhD (Bristol)

Post-licensing director

Healthcare professionals and patients are encouraged to regularly check the Medicines Authority website for product safety updates as these are issued on an ongoing basis.

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