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Review of Numeta G13%E and G16%E started

The European Medicines Agency has started a review of the intravenous (into a vein) nutrition preparations Numeta G13%E and Numeta G16%E following reports of hypermagnesaemia (high blood levels of magnesium) in premature babies.

Numeta 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.

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 marketing authorisation holder is planning to start 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 however remain on the market in situations where no suitable alternative is available. Where such situations arise, Numeta G13%E may continue to be used, but doctors should observe babies for symptoms of hypermagnesaemia such as weakness, breathing problems, hypotension (low blood pressure) and heart problems. In addition, doctors should closely monitor magnesium blood levels and stop Numeta G13%E or reduce the rate of infusion if magnesium levels are high. A letter will be sent out to inform healthcare professionals accordingly.

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.

The Agency invites all stakeholders (e.g. healthcare professionals, patients' organisations, the general public) to submit data relevant to this procedure. Full details are available under the 'data submission' tab.

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More about the medicine

Numeta G13%E and Numeta G16%E (glucose, lipids, aminoacids and electrolytes) are parenteral nutrition solutions. Parenteral nutrition is the use of nutrients and fluids given through a vein to provide nutritional support in patients who cannot be fed by mouth or by enteral nutrition (given directly into the gut bypassing the mouth). Nutritional support in premature neonates is necessary in order to prevent complications such as growth retardation and breathing complications and to promote the normal development of the brain.

Numeta G13%E and Numeta G16%E have been authorised since 2011 via national procedures in the following Member States: Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Spain, Sweden, United Kingdom.

More about the procedure

The review of Numeta G13%E has been initiated at the request of Sweden, under Article 107i of Directive 2001/83/EC, also known as the urgent Union procedure. The PRAC subsequently included Numeta G16%E in the review.

The review is being carried out by the Pharmacovigilance Risk Assessment Committee (PRAC), the Committee responsible for the evaluation of safety issues for human medicines, which will make a set of recommendations. As Numeta G13%E and Numeta G16%E are authorised nationally, the PRAC recommendation will be forwarded to the Co-ordination Group for Mutual Recognition and Decentralised Procedures – Human (CMDh), which will adopt a final position. The CMDh is a medicines regulatory body representing the EU Member States.