HAUTE AUTORITÉ DE SANTÉ

BRIEF SUMMARY OF THE TRANSPARENCY COMMITTEE OPINION

NUMETAH G13% E PREMATURES (ternary mixture)

Minor improvement in the treatment of preterm babies when parenteral nutrition is necessary.

Main points

- NUMETAH G13% E PRETERM has Marketing Authorisation in parenteral nutrition in preterm newborns when oral nutrition or enteral nutrition is impossible, insufficient or contraindicated.
- Owing to the suspension of the Marketing Authorisation for NUMETAH G13%E in December 2013, following cases of hypermagnesaemia, the magnesium concentration was modified; it is now 0.47 mmoL Mg per 300 mL. This new proprietary pharmaceutical product is called NUMETAH G13% E PRETERM.
- In light of this new composition, of the lack of new efficacy data, of the tolerability data for NUMETAH G13%E, and of the recommendation to use as first-line product with Marketing Authorisation for parenteral nutrition, in particular in newborns, NUMETAH G13% E PRETERM retains the same benefit as the old formulation in the management of preterm babies when parenteral nutrition is necessary.

Therapeutic use

- The choice for a parenteral nutritional solution should preferably be a medicinal product with a Marketing Authorisation before compounded preparations.
  Compunded and hospital preparations can only be prescribed if there is no proprietary pharmaceutical product or other appropriate product available that has Marketing Authorisation, given their level of safety. When the needs of patients cannot be covered by proprietary pharmaceutical products, hospital, or so-called “standardised”, preparations should then be prescribed.
  “A la carte” / bespoke compounded preparations, manufactured for a given patient, should be kept as a last resort and/or for specific needs that are not otherwise covered.
- **Role of the medicinal product in the therapeutic strategy**
  NUMETAH G13% E PRETERM is a first-line treatment for when parenteral nutrition is necessary in preterm infants. It may be used in newborns and hospitalised infants receiving parenteral nutrition, especially in hospitals lacking a central unit for making up parenteral nutrition solutions.

Clinical data

- Following the described case of hypermagnesaemia observed in preterm newborns, the magnesium content of NUMETAH G13%E was reduced to become NUMETAH G13% E PRETERM and now corresponds to the new guidelines.
- The efficacy data for NUMETAH G13% E PRETERM are based on an open-label, noncomparative, observational study conducted with the old formulation, NUMETAH G13%E, which showed that with the volumes administered it was possible to obtain supplementation in amino acids, glucose and lipids complying with the international guidelines. No new efficacy data are available with the new formulation of NUMETAH in preterm infants.
- As no studies have been conducted with NUMETAH G13% E PRETERM, there are no new tolerability data.

Benefit of the medicinal product

- The actual benefit* of NUMETAH G13% E PRETERM is substantial.
- NUMETAH G13% E PRETERM retains the minor clinical added value** (CAV IV) of NUMETAH G13%E in the management of preterm newborns when parenteral nutrition is a necessity.
- Recommends inclusion on the list of reimbursable products for hospital use.

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This document was created on the basis of the Transparency Committee Opinion of 20 July 2016 (CT-15334) and is available at **www.has-sante.fr**

* The actual benefit (AB) of a proprietary medicinal product describes its benefit primarily in terms of its clinical efficacy and the seriousness of the condition being treated. The HAS Transparency Committee assesses the AB, which can be substantial, moderate, low or insufficient for reimbursement for hospital use.

** The clinical added value (CAV) describes the improvement in treatment provided by a medicinal product compared with existing treatments. The HAS Transparency Committee assesses the degree of CAV on a scale from I (major) to IV (minor). A level V CAV means “no clinical added value”.