HAUTE AUTORITÉ DE SANTÉ

NUTRITION
New medicinal product
July 2017

BRIEF SUMMARY OF THE TRANSPARENCY COMMITTEE OPINION

JUNIMIN (copper, iodine, manganese, selenium, zinc), trace elements

No clinical benefit for intravenous coverage of trace element needs in premature or full-term newborns, infants and children.

Main points

- JUNIMIN has marketing authorisation in the context of an intravenous nutritional protocol to cover basic trace element needs in premature or full-term newborns, infants and children.
- Its qualitative and quantitative composition, overall compliant with international standards, responds to a medical need that is only partially covered by the medicinal product.
- JUNIMIN is intended to replace SOLUTION INJECTABLE D'OLIGOELEMENTS POUR ENFANTS ET NOURRISSONS AGUETTANT [Aguettant Trace Elements Solution for Injection for Newborns and Children], the composition of which is no longer compliant.
- This is a first-line treatment.

Therapeutic strategy

- Parenteral nutrition is reserved for patients with permanent or temporary intestinal failure, either total or partial. No recommendation is indicated when trace element supplementation is required during parenteral nutrition.
- **Role of the proprietary medicinal product in the therapeutic strategy**
  JUNIMIN can be used in hospitalised newborns and children on parenteral nutrition.
  Its composition provides intake that overall corresponds to international recommendations.
  It is a first-line proprietary medicinal product in children receiving parenteral nutrition who have intestinal failure that does not allow for enteral nutrition.

Clinical data

- No clinical studies having evaluated this proprietary medicinal product are available.
- JUNIMIN contains 20 µg/ml of copper, 100 µg/ml of zinc, 0.5 µg/ml of manganese, 1 µg/ml of iodine, 2 µg/ml of selenium. It does not contain active ingredients in the form of chlorides likely to contribute to the onset of a metabolic acidosis. Its composition overall respects the current recommendations concerning the recommended intake of trace elements in children on parenteral nutrition.
- It is an injectable solution of trace elements intended specifically for the paediatric population (from premature infants to children). Its formula allows it to cover the basic trace element needs of this target population on parenteral nutrition.
- On the other hand, JUNIMIN does not provide all the trace elements whose intake is recommended.

Benefit of the medicinal product

- The actual clinical benefit* of JUNIMIN is substantial.
- Given the qualitative and quantitative composition, overall compliant with international standards, in a population where the need is only partially covered, but in the absence of any clinical study having evaluated the efficacy of this combination of trace elements, JUNIMIN does not provide any clinical added value** (CAV V) in the context of an intravenous nutritional protocol to cover basic trace element needs in premature or full-term newborns, infants and children.
- 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 05 July 2017 (CT-16112) and is available at **www.has-sante.fr**

* The actual clinical benefit (ACB) of a 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 ACB, which can be substantial, moderate, low or insufficient for reimbursement of the medicinal product 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 (equivalent to “no CAV”) means “no clinical added value”.