

Original French opinion adopted by the Transparency Committee

The legally binding text is the original French opinion version

SUMMARY

zinc chloride, copper chloride dihydrate,
sodium selenite, manganese chloride
tetrahydrate, potassium iodide

PEDITRACE,

concentrate for solution for infusion

Inclusion on list

Adopted by the Transparency Committee on 9 April 2025

Summary of opinion

Favourable opinion for reimbursement in “preterm or full-term neonates, infants, children and adolescents in need of intravenous nutrition to meet basal requirements for trace elements.”

Transparency Committee's conclusions

Clinical Benefit

- ➔ Parenteral nutrition in children with total or partial digestive intolerance aims to prevent, in the short and medium term, the clinical consequences of malnutrition or undernutrition that can lead to prolonged hospitalisation, sequelae, or even death.
- ➔ This is a preventive medicinal product, as a replacement for enteral nutrition when the latter is impossible, insufficient or contraindicated.
- ➔ The efficacy/adverse effects ratio is high.
- ➔ It is a first-line treatment, as an alternative to other trace element solutions for parenteral nutrition, in particular JUNIMIN, in the paediatric population.

➔ Public health benefit

Considering:

- the seriousness of clinical situations warranting parenteral nutrition in paediatric patients,
- the met medical need,
- the benefit of having access to balanced trace element supplementation,
- the lack of evidence of an additional impact on morbidity and mortality and on quality of life,
- the lack of evidence of an impact on the organisation of care,

PEDITRACE is unlikely to have an additional impact on public health.

Considering all of these elements, the Committee deems that the clinical benefit of PEDITRACE concentrate for solution for infusion (zinc chloride, copper chloride dihydrate, sodium selenite, manganese chloride tetrahydrate, potassium iodide) is substantial in the MA indication.

The Committee issues a favourable opinion for inclusion of PEDITRACE concentrate for solution for infusion (zinc chloride, copper chloride dihydrate, sodium selenite, manganese chloride tetrahydrate, potassium iodide) in the list of covered drugs for inpatients approved for use in the MA indication and at the MA dosages.

Clinical Added Value

Considering:

- the qualitative and quantitative composition that complies with European recommendations in preterm neonates, but the possible risk of an excessive zinc and/or selenium intake in the other paediatric age groups,
- the well-established use of trace elements in paediatric medicine,
- the absence, however, of clinical data having assessed the efficacy and safety of this trace element combination, and of available use data for PEDITRACE despite this medicinal product being marketed in Sweden,
- an already met medical need,

the Committee deems that PEDITRACE concentrate for solution for infusion (zinc chloride, copper chloride dihydrate, sodium selenite, manganese chloride tetrahydrate, potassium iodide) provides no clinical added value (CAV V) in the MA indication, in the context of an intravenous nutritional protocol to cover the basal requirements for trace elements in preterm or full-term neonates, infants, children and adolescents.