

Original French opinion adopted by the Transparency Committee

The legally binding text is the original French opinion version

SUMMARY

sodium feredetate

FERROSTRANE INFANTS

6.8 mg/mL

syrup

Inclusion on list: First listing

Range supplement

Adopted by the Transparency Committee on 26 March 2025

Summary of opinion

Favourable opinion for reimbursement “in infants in the:

- curative treatment of iron-deficiency anaemia,
- prophylaxis of iron deficiency in preterm infants, twins or infants born to mothers with an iron deficiency, when an adequate dietary iron intake cannot be guaranteed”.

No clinical added value of the new form compared to the form already available.

Transparency Committee's Conclusions

Clinical Benefit

- ➔ The symptoms of iron deficiency are of moderate severity: pallor, headaches, dizziness, but can impair quality of life. In newborn infants, iron deficiency can cause developmental disorders.
- ➔ The efficacy/adverse effects ratio of this proprietary medicinal product is high.
- ➔ It is a curative and/or preventive medicinal product.
- ➔ It is a first-line treatment.
- ➔ There are several oral iron alternatives.

→ Public health benefit

FERROSTRANE INFANTS 6.8 mg/mL (sodium feredetate) syrup (with a new 5 mL dosing device, graduated every 0.1 mL) is unlikely to have an additional impact on public health compared to the FERROSTRANE 0.68 PERCENT (sodium feredetate) syrup form, already available.

The Committee considers that the clinical benefit of FERROSTRANE INFANTS 6.8 mg/mL (sodium feredetate) syrup is substantial in the MA indications.

The Committee issues a favourable opinion for inclusion in both the list of covered drugs for outpatients and the list of covered drugs for inpatients approved for use in the indications and at the MA dosages.

→ Recommended reimbursement rate for inclusion in the list of covered drugs for outpatients: 65%

Clinical Added Value

This medicinal product is a range supplement that does not provide any clinical added value (CAV V) compared to the form already listed.