HAUTE AUTORITÉ DE SANTÉ

HAEMATOLOGY
New medicinal product
December 2016

BRIEF SUMMARY OF THE TRANSPARENCY COMMITTEE OPINION

MONOVER (iron isomaltoside 1000), injectable iron

No clinical benefit demonstrated when compared with other iron-containing medicinal products administered by injection

Main points

- MONOVER has a Marketing Authorisation in the treatment of iron deficiency anaemia when oral iron preparations are ineffective or cannot be used, or when there is a clinical need to quickly restore the iron reserves.
- MONOVER has a chemical structure (dextran-free iron) that allows administration of a single high dose of iron with no prior test.
- The way it is administered (rapid administration and high single dose) can have a positive impact on the organisation of care and the management of patients at the hospital (limits the number of injections and visits required for the correction of iron deficiency).
- MONOVER has not been compared with FERINJECT.

Therapeutic use

First-line therapeutic management of patients with iron deficiency is oral iron supplementation.
In case of proven intolerance of oral iron preparations, if oral iron treatment has been shown to be ineffective, or if there is a clinical need to deliver iron to iron stores rapidly, treatment with injectable iron salts is recommended.
In patients on haemodialysis, intravenous administration is the optimal route for administration of iron.
Other treatments of severe iron deficiency anaemia are transfusion, which should be avoided as much as possible, and erythropoiesis-stimulating agents, which must be administered, if necessary, together with the injectable iron.

Role of the proprietary medicinal product in the therapeutic strategy

As with FERINJECT, in case of demonstrated intolerance of oral iron preparations, if oral iron treatment has been shown to be ineffective, or if there is a clinical need to deliver iron to iron stores rapidly, MONOVER is a first-line medicinal product.

Clinical data

- The efficacy of MONOVER was compared to that of iron sucrose (VENOFER) in two non-inferiority studies, one in patients with chronic renal disease on haemodialysis, and the other in patients with iron deficiency anaemia, intolerant or not responding to oral iron treatment or requiring a rapid restoration of iron stores.
  The first study demonstrated the non-inferiority of MONOVER compared to VENOFER on the proportion of patients who maintained an Hb concentration between 9.5 and 12.5 g/dL at 6 weeks.
  The superiority of MONOVER compared to VENOFER on the improvement of haemoglobin levels observed in the second study cannot be considered as demonstrated, given the higher cumulative iron doses administered in the MONOVER group than in the VENOFER group (45% higher dose).

- The efficacy of MONOVER was also evaluated in three randomised, open-label, non-inferiority, comparative studies versus oral iron administered in patients with iron deficiency anaemia of mixed origin.
  These studies do not demonstrate the superiority of MONOVER compared with iron-based medicinal products administered orally on the change in Hb level and confirm that injectable forms of iron must be prescribed in strict compliance with the Marketing Authorisation, namely when oral administration is impossible or inappropriate.

- The safety profile of MONOVER seems to be similar to that of other iron sucrose-based proprietary medicinal products, with a risk of severe hypersensitivity reactions common to all injectable irons.
- No study has compared the efficacy or safety of MONOVER to that of FERINJECT and no study has documented the impact on morbidity and mortality of MONOVER compared with treatments currently used (VENOFER and FERINJECT).

Special prescribing conditions

- Medicinal product reserved for hospital use.

Benefit of the medicinal product

- The actual benefit* of MONOVER is substantial.
- MONOVER does not provide clinical added value** (CAV V) by comparison with other available injectable irons (FERINJECT, VENOFER and other iron sucrose proprietary medicinal products) in the treatment of iron deficiency anaemia when oral iron preparations are ineffective or cannot be used, or when there is a clinical need to quickly restore the iron reserves.
- 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 14 December 2016 (CT-15570) and is available at **www.has-sante.fr**

* The actual benefit (AB) 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 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”.