HAUTE AUTORITÉ DE SANTÉ

NEPHROLOGY
New medicinal product
February 2015

BRIEF SUMMARY OF THE TRANSPARENCY COMMITTEE OPINION

VELPHORO (sucroferric oxyhydroxide), antihyperphosphatemic

No clinical benefit demonstrated in the treatment of hyperphosphataemia in patients on dialysis for chronic kidney failure compared with sevelamer carbonate

Main points

- VELPHORO has Marketing Authorisation in the control of serum phosphorus levels in chronic kidney failure patients on haemodialysis or peritoneal dialysis
- Its non-inferiority compared with RENVELA (sevelamer carbonate) was demonstrated in terms of control of serum phosphorus levels. Adverse events were observed more commonly with VELPHORO than with sevelamer carbonate, especially those of a gastrointestinal nature, further justifying early treatment discontinuations

Therapeutic use

- In patients on dialysis for chronic kidney failure, hyperphosphataemia is associated with a heightened risk of morbidity, and bone and cardiovascular morbidity in particular. Despite measures to control this hyperphosphataemia through diet and by dialysis, most often, phosphate chelating agents need to be used. In this situation, calcium salts, sevelamer or lanthanum carbonate are used.
- **Role of the medicinal product in the therapeutic strategy**

  VELPHORO is an alternative to the other phosphate chelating agents in the treatment of hyperphosphataemia combined with chronic kidney failure treated by haemodialysis or peritoneal dialysis.

Clinical data

- A randomised study evaluated VELPHORO versus RENVELA (sevelamer carbonate) in dialysis patients,
- After 12 weeks of treatment, VELPHORO was non-inferior to sevelamer carbonate in terms of lowering serum phosphorus levels: -0.71 mmol/L in the VELPHORO group (n=461) versus -0.79 mmol/L (n=224). During the first 6 months of treatment, VELPHORO required fewer tablets to be taken, an average of 3.1 versus 8.1 tablets per day.
- Overall, VELPHORO was less well tolerated than sevelamer carbonate, with a more common occurrence of adverse effects (39.6% versus 19.8%), particularly gastrointestinal. The adverse effects thus further justified more early discontinuations of treatment with VELPHORO than with sevelamer (15.7% versus 6.6%).
- Only a small amount of iron would be released by VELPHORO and absorbed by the body. However, data on the risk of iron overload remain limited, particularly in the long term. The risk management plan for VELPHORO provides for special monitoring of this risk.

Benefit of the medicinal product

- The actual benefit* of VELPHORO is substantial.
- VELPHORO does not provide clinical added value** (CAV V) in the control of serum phosphorus levels in chronic kidney failure patients on dialysis.
- Recommends inclusion on the list of reimbursable products for supply by pharmacists and for hospital use.

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This document was created on the basis of the Transparency Committee Opinion of 04 February 2015 (CT-13935) and is available at **www.has-sante.fr**

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[i] * 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".