

## **Re-evaluation of the pharmacotherapeutic value of calcium acetate/ magnesium carbonate (OsvaRen®) for the treatment of hyperphosphatemia.**

The Medicinal Products Reimbursement Committee (CFH) has performed a re-evaluation for the combination product calcium acetate/ magnesium carbonate (OsvaRen®). Calcium acetate/ magnesium carbonate is indicated for the treatment of hyperphosphatemia. Magnesium carbonate has been added to calcium acetate to minimize the daily calcium intake for phosphate binding.

The Committee has previously evaluated calcium acetate/ magnesium carbonate in April 2010 ("CFH-rapport 10/10", 26 April 2010). Then the Committee concluded that calcium acetate/ magnesium carbonate potentially poses less risks due to the lower calcium dosage, but that these effects have not been established on clinically relevant endpoints. It was decided that calcium acetate/ magnesium carbonate may be considered replaceable with calcium acetate, and this decision was based on a direct comparison with calcium carbonate and an extrapolation to other calcium containing phosphate binders. The manufacturer does not agree with the verdict of the Committee and requests to grant calcium acetate/ magnesium carbonate an added therapeutic value in comparison with calcium acetate based on newly published data. The Committee has focused in this re-evaluation on these new data. The data do not provide information regarding clinically relevant differences between calcium acetate/ magnesium carbonate and calcium monotherapy, but they relate to a direct comparison with the product sevelamer. The Committee maintains her verdict that the therapeutic value of OsvaRen® is comparable with that calcium acetate.