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Clinical Expert Summary Sucroferric oxyhydroxide (Velphoro[®]▼) 500 mg chewable tablets

Sucroferric oxyhydroxide (Velphoro[®]▼) for the control of serum phosphorus levels in adult chronic kidney disease (CKD) patients on haemodialysis (HD) or peritoneal dialysis (PD).

Sucroferric oxyhydroxide (Velphoro[®]▼) should be used within the context of a multiple therapeutic approach, which could include calcium supplement, 1,25-dihydroxy vitamin D3 or one of its analogues, or calcimimetics to control the development of renal bone disease.

1. Existing guidelines

Individual renal units in Wales may have local guidelines on management of hyperphosphataemia. It is the opinion of one expert that evidence in this clinical area is sparse, conflicting, controversial and incomplete which impairs the production of agreed protocols even within a single unit. There is national guidance on target levels for serum phosphate to achieve in CKD patients (e.g. Renal Association Standards) but they are not specific on best practice for pharmacological management. It is considered that the National Institute of Health and Care Excellence (NICE) Clinical Guideline on Hyperphosphataemia in CKD (2013) has not yet had a significant impact on prescribing practice in Wales.

2. Disease prevalence/incidence

It was estimated that in total there are approximately 550 haemodialysis patients and 100 peritoneal dialysis patients under the care of Cardiff nephrologists, who offer services to Cardiff and Vale, Cwm Taf and Aneurin Bevan Health Boards. Most of these will be hyperphosphataemic and a large proportion (66–75%) will currently be taking phosphate binders. Sucroferric oxyhydroxide is a potential option for all these patients.

Another expert stated that there would be approximately 300 patients in a population of 300,000 in their locality.

3. Current treatment options

The calcium based binders highlighted by experts were calcium carbonate (e.g. Calcichew[®]), calcium acetate (e.g. Phosex[®]) and calcium acetate plus magnesium carbonate (e.g. Osvaren[®]). Calcium-free binders included sevelamer hydrochloride (e.g. Renagel[®]), sevelamer carbonate (e.g. Renvela[®]), lanthanum carbonate (e.g. Fosrenol[®]) and aluminium hydroxide (e.g. Alucaps[®]). With the exception of aluminium hydroxide (prescribed less frequently due to concerns about long term safety), all the above medicines are prescribed routinely in Wales. The main consideration highlighted when prescribing phosphate binders was whether to select a calcium or calcium-free agent. Generally, calcium-based are regarded as first line (a point endorsed by the NICE guideline), but prescribing of sevelamer and lanthanum binders appears to be increasing, either as a second line agent after calcium-based binders or, increasingly, as a first line option in selected patients. This is considered by one expert as an important and controversial issue in the nephrology community because the latter two treatments are significantly more expensive than standard therapies.

4. Unmet needs

It was highlighted that other causes of hyperphosphataemia such as sarcoidosis, hypoparathyroidism, acromegaly, cytotoxic therapy and respiratory acidosis are areas of unmet need in relation to this condition.

5. Knowledge of product in given indication

Sucroferric oxyhydroxide would sit alongside sevelamer and lanthanum as a calcium free binder. In the early stages it would be prescribed for patients as a later option when existing binders are not tolerated. Eventually, as experience grows (e.g. in terms of benefits and side effects) prescribing may increase.

Having new and novel phosphate binders is a positive development for nephrology teams because it increases the range of available options. The focus is on finding a phosphate binder for an individual patient that is palatable, well tolerated and effective at achieving target levels of serum phosphate. This is a far from easy task and phosphate binders are beset with problems of poor adherence to treatment so alternative options are welcome.

Cost is considered to be a key issue. Sevelamer and lanthanum binders are considerably more expensive than calcium carbonate and acetate, so it was noted that if sucroferric oxyhydroxide can narrow this cost-effectiveness gap then levels of prescribing will increase at a faster rate.

It should be noted that one expert involved in compiling this response declared a personal specific interest in relation to sucroferric oxyhydroxide for the indication under consideration.