Scottish Medicines Consortium
Providing advice about the status of all newly licensed medicines
www.scottishmedicines.org.uk
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NHS SCOTLAND

Resubmission

Product Update

sevelamer carbonate 800mg film-coated tablets and 2.4g of anhydrous powder for oral suspension (Renvela®) (No: 641/10)

Genzyme Therapeutics Ltd

04 March 2011

The Scottish Medicines Consortium (SMC) has completed its assessment of the above product and advises NHS Boards and Area Drug and Therapeutic Committees (ADTCs) on its use in NHS Scotland. The advice is summarised as follows:

ADVICE: following an abbreviated submission

sevelamer carbonate (Renvela®) is accepted for restricted use within NHS Scotland.

Indication under review: for the control of hyperphosphataemia in adult patients receiving haemodialysis or peritoneal dialysis.

SMC restriction: the second-line management of hyperphosphataemia in adult patients receiving haemodialysis.

Sevelamer carbonate has been shown to be therapeutically equivalent to sevelamer hydrochloride in reducing serum phosphorus in patients with chronic kidney disease on haemodialysis. For patients in whom sevelamer hydrochloride is an appropriate choice of phosphate binder, the carbonate salt provides an alternative at no additional cost.

Sevelamer carbonate is also indicated for the control of hyperphosphataemia in adult patients with chronic kidney disease not on dialysis with serum phosphorus ≥ 1.78 mmol/L. As the manufacturer's submission related only to the control of hyperphosphataemia in adult patients receiving haemodialysis SMC cannot recommend the use of sevelamer carbonate in pre-dialysis patients or in peritoneal dialysis patients.

Advice context:

No part of this advice may be used without the whole of the advice being quoted in full.

This advice represents the view of the Scottish Medicines Consortium and was arrived at after evaluation of the evidence submitted by the company. It is provided to inform the considerations of Area Drug & Therapeutics Committees and NHS Boards in Scotland in determining medicines for local use or local formulary inclusion. This advice does not override the individual responsibility of health professionals to make decisions in the

exercise of their clinical judgement in the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

This assessment is based on data submitted by the applicant company up to and including 13 January 2011.

Chairman
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