SHARED CARE GUIDELINES FOR THE USE OF SEVELAMER (RENAGEL®) IN THE MANAGEMENT OF HYPERPHOSPHATAEMIA IN PATIENTS RECEIVING HAEMODIALYSIS

INDICATION

Sevelamer is indicated for the control of hyperphosphataemia in adult patients receiving haemodialysis or peritoneal dialysis. It should be used within the context of a multiple therapeutic approach, which could include calcium supplements, 1,25 – dihydroxy Vitamin D_3 or one of its analogues to control the development of renal bone disease.

Patients with chronic renal failure (CRF) are unable to excrete phosphate. A build up of phosphate enhances parathyroid activity and leads to the calcification of arteries, thus significantly contributing to the excess cardiovascular morbidity in these patients, especially in the younger age groups. Adequate control of serum phosphate levels is therefore essential for the prevention of vascular and cardiac calcification in patients with renal failure. Sevelamer is a non-calcium/aluminium binder.

This shared care guideline is intended to apply to adult patients on haemodialysis who have been initiated on sevelamer by the Dorset Renal Unit for the management of hyperphosphataemia. It has been based on the treatment guideline that has been developed by the Dorset Renal Unit for managing hyperphosphataemia in renal patients. Prescribers are referred to the treatment guideline for further guidance on the use of phosphate binders for patients with chronic renal failure.

In accordance with the local guideline, Sevelamer will be prescribed for the following patients receiving haemodialysis:

- transplantable patients with severe hyperparathyroidism (increased calcium, phosphate, and PTH levels) either solely, or in combination with a calcium containing binder (depending on serum calcium levels), to avoid the risk of cardiac and vascular damage, prior to parathyroidectomy;
- other dialysis patients with a reasonable prognosis on dialysis (life expectancy greater than 5 years) who are not transplantable if they develop hyperparathyroidism prior to parathyroidectomy.

Sevelamer should be prescribed until patients have had a parathyroidectomy and calcium levels have normalised.

Note: Younger fitter patients, suitable for transplantation, and without severe hyperparathyroidism, may be safely treated with calcium containing binders. Non-transplantable patients with a life expectancy on dialysis of less than 1 year should be treated with aluminium based phosphate binders if they develop severe hyperparathyroidism.

AREAS OF RESPONSIBILITY FOR SHARED CARE

This shared care agreement outlines suggested ways in which the responsibilities for managing the prescribing of sevelamer can be shared between the specialist and general practitioner (GP). GPs are invited to participate. If the GP is not confident to undertake these roles, then he or she is under no obligation to do so. In such an event, the total clinical responsibility for the patient for the diagnosed condition remains with the specialist. If a specialist asks the GP to prescribe this drug, the GP should reply to this request as soon as practicable.

Sharing of care assumes communication between the specialist, GP and patient. The intention to share care is usually explained to the patient by the doctor initiating treatment. It is important that patients are consulted about treatment and are in agreement with it.

The doctor who prescribes the medication legally assumes clinical responsibility for the drug and the consequences of its use.

REFERRAL AND INITIATION

Shared Care is only appropriate if it provides the optimum solution for the patient.

- Patients will only be referred to the GP once the GP has agreed in each individual case
- Arrangements to transfer treatment from secondary to primary care may be made from 3 months after initiation of treatment, once the condition has been stabilised

Specialist Responsibilities	
1	To assess the patient and establish the need for sevelamer.
2	To initiate and titrate therapy to determine optimal dose level according to the agreed protocol for the use of phosphate binders in renal patients. **The first three months of treatment will be prescribed through the Dorset Renal Unit.**
3	To obtain consent from the patient's GP to continue prescribing once treatment has been stabilised ensuring they are provided with appropriate prescribing information and any additional information requested.
4	To review patients regularly in clinic, monitor phosphate and calcium levels and undertake all necessary monitoring.
5	To be available for advice if the patient's condition changes and to provide the GP with up-to-date information when changes are made to the patient's prescription following consultant review.
6	To ensure that procedures are in place for the rapid re-referral of the patient by the GP.
7	To ensure the patient/ carer has given informed consent to their treatment.
8	To discontinue treatment if no longer thought to be beneficial

General Practitioner Responsibilities	
1	Initially, to refer the patient for specialist advice.
2	Where appropriate, to continue to supply sevelamer as per doses agreed with specialist after the initial three month titration period and once relevant information has been received and agreed with the consultant
3	To deal with general health issues of the patient.
4	To liaise with the consultant regarding any complications of treatment.

Patient's role (or that of carer)	
1	Report to the specialist or GP if he or she does not have a clear understanding of the treatment.
2	Attend appropriate consultant and GP appointments
3	Share any concerns in relation to treatment with sevelamer
4	Use written and other information on the medication, including taking sevelamer with meals and adhering to their prescribed diets. The tablets must be swallowed whole. Do not chew.
5	Seek help urgently if suspect side effects, or otherwise unwell.

SUPPORTING INFORMATION

Adults and elderly (> 65 years)

For patients who are not on phosphate binders, dosage is determined individually based on serum phosphate concentration as indicated in the table below:

Serum phosphate level in patients not on phosphate binders	Starting dose of sevelamer 800 mg tablets
1.76 – 2.42 mmol/l (5.5-7.5 mg/dl)	1 tablet, 3 times per day
> 2.42 mmol/l (>7.5 mg/dl)	2 tablets, 3 times per day

If sevelamer is prescribed as an alternative phosphate binder, sevelamer should be given in equivalent doses on a mg weight basis compared to the patient's previous calcium based phosphate binder. Serum phosphate levels should be closely monitored and the dose of sevelamer adjusted accordingly with the goal of lowering serum phosphate to 1.76 mmol/l (5.5 mg/dl) or less. Serum phosphate should be tested every two to three weeks until a stable serum phosphate level is reached and on a regular basis thereafter.

The dose range may vary between 1 and 5 800 mg tablets per meal. The average actual daily dose used in the chronic phase of a one year clinical study was 7 grams of sevelamer.

Contraindications
Contraindications included in the current summary of product characteristics include:
- Bowel obstruction;
- Hypophosphataemia;
- Hypersensitivity to sevelamer or to any of the excipients.

Special Warnings
The manufacturer's SPC includes:

- Caution in pregnancy and breastfeeding;
- Caution in gastrointestinal disorders.

In very rare cases, intestinal obstruction and ileus/subileus have been observed in patients during treatment with sevelamer. Constipation may be a preceding symptom. Patients should be advised to inform their doctor or pharmacist if constipation occurs. Patients who are constipated should be monitored carefully and treatment reviewed in patients who develop severe constipation.

Sevelamer is **not** licensed for use in children under the age of 18, predialysis patients or in patients receiving peritoneal dialysis.

Data on the chronic use of sevelamer for over one year are **not** available.

Side Effects
Common side effects are associated with the gastrointestinal system and may include nausea, diarrhoea, feelings of bloatedness, dyspepsia and constipation.

The summary of product characteristics should be consulted for full information with respect to adverse effects and drug interactions.

Drug Interactions
Sevelamer should not be taken simultaneously with ciprofloxacin. Sevelamer may affect the bioavailability of other medicinal products. When administering any medicinal product where a reduction in the bioavailability could have a clinically significant effect on safety or efficacy, the medicinal product should be administered at least one hour before or three hours after sevelamer, or the physician should consider monitoring blood levels

Drug costs: Sevelamer 800mg (1-5 tablet tds, 28 days treatment) £58.99 - £294.93
Drug Tariff, June 2009

References

1. *Renagel*® (Sevelamer) tabs 800mg (Genzyme) Summary of Product Characteristics September 2008

The manufacturer's summary of product characteristics (SPC) and the most current edition of the British National Formulary should be consulted for full information on contra-indications, warnings, side-effects and drug interactions.

Written By	**Renal sub-group**	**June 2009**
Approved By	**Bournemouth, Dorset and Poole Prescribing Forum**	**June 2009**

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