SHARED CARE GUIDELINES FOR THE USE OF LANTHANUM (FOSRENOL®) IN THE MANAGEMENT OF HYPERPHOSPHATAEMIA IN RENAL PATIENTS RECEIVING HAEMODIALYSIS OR CAPD

INDICATION

Lanthanum is indicated as a phosphate binding agent for use in the control of hyperphosphataemia in chronic renal failure patients on haemodialysis or continuous ambulatory peritoneal dialysis (CAPD).

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. Lanthanum is a non-calcium/aluminium binder.

This shared care guideline is intended to apply to adult patients who have been initiated on lanthanum 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, Lanthanum will be prescribed for the following patients:

- 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.

Lanthanum 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 lanthanum.
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 lanthanum 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)

Lanthanum should be taken with or immediately after food, with the daily dose divided between meals. Patients should adhere to recommended diets in order to control phosphate and fluid intake. Lanthanum is presented as a chewable tablet therefore avoiding the need to take additional fluid. Serum phosphate levels should be monitored and the dose of lanthanum titrated every 2-3 weeks until an acceptable serum phosphate level is reached, with regular monitoring thereafter.

Control of serum phosphate level has been demonstrated at doses starting from 750 mg per day. The maximum dose studied in clinical trials, in a limited number of patients, is 3750mg. Patients who respond to lanthanum therapy; usually achieve acceptable serum phosphate levels at doses of 1500 – 3000 mg lanthanum per day.

Contraindications
Included in the current Summary of Product Characteristics:

- Hypersensitivity to lanthanum carbonate hydrate or to any of the excipients;
- Hypophosphataemia;

Special Warnings
The manufacturer's SPC includes:

- Caution in pregnancy and breastfeeding;
- Caution in gastrointestinal disorders. Patients with acute peptic ulcer, ulcerative colitis, Crohn's disease or bowel obstruction were not included in clinical studies. Lanthanum should be used in these patients following careful assessment of benefit and risk.

Serum calcium levels should be monitored at regular time intervals for this patient population for hypocalcaemia and appropriate supplements given where this occurs.

The effect of hepatic impairment on lanthanum pharmacokinetics has not been assessed. Due to its mechanism of action and the lack of liver metabolism doses in hepatic impairment should not be modified, but patients should be monitored carefully

Lanthanum should be discontinued if hypophosphataemia develops.

Abdominal x-rays of patients taking lanthanum carbonate may have a radio-opaque appearance typical of an imaging agent.

Lanthanum is **not** licensed for use in children.

Side Effects
The most commonly reported adverse drug reactions, with the exception of hypocalcaemia, are gastrointestinal in nature; these are minimized by taking lanthanum with food and generally abate with time with continued dosing.

May induce dizziness and vertigo, which may impair the ability to drive and use machinery

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

Drug Interactions
It is recommended that compounds, which are known to interact with antacids, should not be taken within 2 hours of dosing with lanthanum (e.g. chloroquine, hydroxychloroquine and ketoconazole).
Interactions with drugs such as tetracycline, doxycycline and the floxacins are theoretically possible and if these compounds are to be co-administered, it is recommended that they not be taken within 2 hours of dosing with lanthanum.

Drug costs: £114.13 - £161.33 (dose range of 500mg- 1gm tds for 28 days supply)
Drug Tariff June 2009

References

1. *Fosrenol*® (Lanthanum) tabs (Shire Pharmaceuticals Ltd) Summary of Product Characteristics August 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 subgroup**	**June 2009**
Approved By	**Bournemouth, Dorset and Poole Prescribing Forum**	**June 2009**

Review Date	**April 2011 or before in the light of new evidence and/or recommendations**