**LINCOLNSHIRE CLINICAL COMMISSIONING GROUPS in association with UNITED LINCOLNSHIRE HOSPITALS TRUST**

# SHARED CARE GUIDELINE: LANTHANUM in the management of Hyperphosphataemia in adult patients receiving haemodialysis or peritoneal dialysis who did not respond to or were unable to tolerate treatment with sevelamer and for controlling hyperphosphataemia associated with chronic kidney disease (CKD)

## General Principles

Shared Care Responsibilities:

In its guidelines on responsibility for prescribing (circular EL (91) 127) between hospitals and general practitioners, the Department of Health has advised that legal responsibility for prescribing lies with the doctor who signs the prescription. (*BNF* 68 September 2014 - March 2015, pg.5)

Aims:

(1) The aim of shared care guidelines is to provide information and/or guidance to GPs and hospital staff relating to the potentially complex implications of sharing patient care for a specific drug between primary and secondary/tertiary care.

(2) Specific shared care guidance should be available for any high cost drug, high-risk drug therapy or device that may be prescribed for a patient following specialist referral. Such guidance will only be produced where shared care is considered an appropriate option.

(3) Each guideline will include a clear statement of the responsibilities of both the GP and the specialist unit within the overall provision of the treatment to the patient.

(4) Shared care guidelines will ensure that the GP has sufficient information available to undertake to prescribe a specialist treatment if s/he so wishes. It is not the intention of these guidelines to insist that GPs prescribe such treatment and any doctor who does not wish to accept clinical or legal responsibility to prescribe such a drug is under no obligation to do so. Nonetheless the development of a shared care guideline will only be undertaken within the context of a broad acceptance between the Lincolnshire Prescribing and Clinical Effectiveness Forum (PACEF) and secondary/tertiary care that GP prescribing of such a treatment is appropriate within the constraints of formal shared care. Any drug approved for the development of a shared care guideline will automatically be classified as amber on the Lincolnshire Traffic Lights List and, if high-cost, will be supported financially through the High Cost Drugs Reserve. Thus there should be no financial reason why a GP should be deterred from prescribing a high cost drug under a shared care guideline.

**Further copies**

Further copies of any guideline in this series are available from members of the Greater East Midlands Commissioning Support Unit (GEMS) Prescribing & Medicines Optimisation Team

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## Principles of shared care

The General Medical Council published their Good Practice In Prescribing And Managing Medicines which came into effect 25th February 2013. A section of the guidance provides recommendations for the sharing of care which applies to any instance when care is shared between different services.

**Good practice recommendation 35.**

- Decisions about who and who should take responsibility for continuing care or treatment after initial diagnosis or assessment should be based on patients best interest rather than on convenience or the cost of the medicine and associated monitoring or follow-up

**Good practice recommendation 36.**

- Shared care requires the agreement of all parties including the patient. Effective communication and continuing liaison between all parties to a shared care agreement is essential.

**Good practice recommendation 37.**

- If you prescribe at the recommendation of another doctor, nurse or other healthcare professional, you must satisfy yourself that the prescription is needed, appropriate for the patient and within the limits of your competence.

**Good practice recommendation 38.**

- If you delegate assessment of a patients' suitability for a medicine, you must be satisfied that the person to whom you delegate has the qualifications, experience, knowledge and skills to make the assessment. You must give them enough information about the patient to carry out the assessment required

**Good practice recommendation 39.**

- In both cases, you will be responsible for any prescription you sign.

**Good practice recommendation 40.**

- If you recommend that a colleague, for example a junior doctor or general practitioner, prescribes a particular medicine for a patient, you must consider their competence to do so. You must satisfy yourself that they have sufficient knowledge of the patient and the medicine, experience (especially in the case of junior doctors) and information to prescribe. You should be willing to answer their questions and otherwise assist them in caring for the patient, as required

**Good practice recommendation 41**

- If you share responsibility for a patient's care with a colleague, you must be competent to exercise your share of clinical responsibility.

You should:

a) Keep yourself informed about the medicines that are to be prescribed for the patient
b) Be able to recognise serious and frequently occurring adverse side effects
**c)** Make sure appropriate clinical monitoring arrangements are in place and that the patient and the healthcare professionals involved understand them
d) Keep up to date with relevance guidance on the use of the medicines and on the management of the patient's condition

**Good practice recommendation 42**

- In proposing a shared care arrangement, specialists may advise the patient's general practitioner which medicine to prescribe. If you are recommending a new or rarely prescribed medicine you should specify the dosage and means of administration and agree a protocol for treatment. You should explain the use of unlicensed medicines and departures from authoritative guidance or recommended treatments and provide both the general practitioner and the patient with sufficient information to permit the safe management of the patient's condition.

**Good practice recommendation 43**

- If you are uncertain about your competence to take responsibility for the patients continuing care you should seek further information or advice from the clinician with whom the patient's care is shared or from another experienced colleague. If you are still not satisfied you should explain this to the other clinician and to the patient and make appropriate arrangements for their continuing care.

## Drug Details

Approved Name: **Lanthanum carbonate**
Brand Name: Fosrenol
Form and Strength: 250mg, 500mg, 750mg and 1g chewable tablets. 750mg and 1000mg oral powder sachets.

## Specialist Responsibilities

The specialist secondary/tertiary care service will:

1. Send a letter to the GP requesting that the GP participates in shared care. As part of the communication the GP should be signposted to where they can find a copy of the shared care protocol e.g. the PACEF website http://lincolnshire-pacef.nhs.uk/lincolnshire-prescribing-and-clinical-effectiveness-forum-
2. Carry out baseline measurements of U&Es, calcium, phosphate and parathyroid hormone levels and before commencing therapy will communicate these to the GP.
3. Provide patient with pre-treatment information leaflet and patient held record booklet.
4. Provide the GP with clear instructions as to the initial dose of lanthanum including details of any dose titration that might be required and when the patient will next be reviewed in clinic.
5. Periodically (at one to six monthly intervals in clinic) review the patient's clinical condition.
6. Communicate promptly any changes in biochemistry monitoring and modification of lanthanum dose to the GP.
7. Have a mechanism in place to receive rapid referral of a patient from the GP in the event of deteriorating clinical condition.
8. Follow up any adverse drug reactions reported by the GP and report back to the GP.
9. Advise the GP in stopping treatment.

## GP Responsibilities

The GP will:

1. Notify the consultant in writing, within two weeks, if they agree to share care.
2. Initiate treatment with lanthanum according to instructions provided by the

specialist service.
3. Provide repeat prescriptions according to recommendations on dosage by the renal unit, Lincoln County Hospital.
4. Monitor the patients overall health and wellbeing.
5. Monitor the patient for adverse drug reactions and remain vigilant to the risk of potential drug interaction.
6. Carry out any investigations that are communicated and deemed appropriate.

## Referral Criteria

1. Patients will have been stabilised on their Vitamin D analogues and other phosphate binders.
2. The specialist will have carried out an assessment of efficacy.

## Licensed Indications

Lanthanum carbonate is indicated as a phosphate binding agent for use in the control of hyperphophataemia in chronic renal failure patients on haemodialysis or continuous ambulatory peritoneal dialysis (CAPD).
Lanthanum carbonate is also indicated in adult patients with chronic kidney disease not on dialysis with serum phosphate levels ≥1.78 mmol/L in whom a low phosphate diet alone is insufficient to control serum phosphate levels.

## Recommended Dosage and Administration

250mg-1g with or immediately after each meal. Tablets must be chewed completely and not swallowed whole. To aid with chewing the tablets may be crushed
Oral powder is intended to be mixed with a small quantity of soft food (the manufacturers suggest applesauce) and consumed within 15 minutes. The sachet should not be opened until ready to use. The oral powder is insoluble and **must not** be dissolved in liquid for administration.
Patient's who respond to lanthanum therapy; usually achieve acceptable serum phosphate levels at doses of 1500-3000mg lanthanum per day.

Use only in patients whose calcium is 2.4mmol/l or greater, who are intolerant of sevelamer.

## Background Pharmacology

Lanthanum carbonate is a non-absorbed, non-calcium containing phosphate binder. On administration with food, lanthanum carbonate forms lanthanum phosphate which does not readily pass through the gastrointestinal tract into the blood. As a result, phosphate absorption is decreased. Serum phosphate is lowered. Lanthanum carbonate has low systemic absorption and avoids the risk of systemic adverse effects.

## Preparations Available

Chewable tablets containing 250mg, 500mg, 750mg or 1gram of lanthanum carbonate.
Oral powder sachets containing 750mg or 1gram of lanthanum carbonate.

## Adverse Effects

Black triangle drug – report any adverse effect to CHM.
Commonly – hypocalcaemia, headache and gastrointestinal disturbances including nausea, vomiting, abdominal pain, constipation, diarrhoea, dyspepsia and flatulence. Other adverse effects that occur less commonly are anorexia, increased appetite, taste disturbance, dry mouth, thirst, stomatitis, chest pain, peripheral oedema, dizziness, vertigo, asthenia, fatigue, malaise, hyperglycaemia, hyperparathyroidism, hypercalcaemia, hypophosphataemia, eosinophilia, arthralgia, myalgia, osteoporosis, sweating, alopecia, pruritis and erythematous rash, accumulation of lanthanum in the bone and transient changes in QT interval. For full list of reported adverse effects refer to SPC.

## Drug Interactions

Antibacterials – Lanthanum possibly reduces absorption of quinolones give at least 2 hours before or 4 hours after lanthanum.
Antifungals - Lanthanum possibly reduces absorption of ketoconazole give at least 2 hours apart.
Antimalarials - Lanthanum possibly reduces absorption of chloroquine and hydroxychloroquine give at least 2 hours apart.
Thyroid hormones Lanthanum possibly reduces absorption of levothyroxine give at least 2 hours apart.

## Precautions and Contraindications

Precautions
Pregnancy Manufacturer advises avoid as toxicity reported from animal studies.
Breast-feeding. Manufacturer advises caution as no information available. Use only if benefits outweigh risks to the baby.
Use with caution in ; - acute peptic ulcer, ulcerative colitis, Crohn's disease, bowel or biliary obstruction.
Hepatic impairment - use with caution, lanthanum excreted in the bile possible accumulation in obstructive jaundice.
Contraindication
Hypersensitivity to lanthanum carbonate, or any of the excipients in the product.
Hypophosphataemia.

## Monitoring

Baseline:
Blood levels of U&Es, calcium and phosphate at each clinic visit, parathyroid hormone levels every 3 months. All monitoring is the responsibility of the renal services (see specialist responsibilities page 2).

**Treatment should be stopped and advice from the supervising specialist sought if:**
- There is deterioration in the clinical condition and/or the patient experiences major side-effects.
- Serum calcium levels fall outside the range of 2.2 to 2.6mmol/l

## Indication of Likely Cost of Therapy in Primary Care

One month's supply (excluding VAT):
Lanthanum tablets
500mg three times daily: £124.06

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|---|---|
| 750mg three times daily: | £182.60 |
| 1000mg three times daily: | £193.59 |
| Lanthanum powder sachets | |
| 750mg three times daily | £182.60 |
| 1000mg three times daily | £193.59 |

## Information Given to the Patient

Patient information leaflet with dispensed product.

## Contact Details

**Consultant Nephrologists**

Dr Little's Secretary: 01522 573961
Dr Hardy's Secretary: 01522 572335
Dr Williams' Secretary: 01522 573961

**Renal Pharmacist**

Caroline Taylor: 01522 573598
Renal Pharmacist
County Hospital

## References

BNF 68 September 2014.
SPC Fosrenol chewable tablets, Shire Pharmaceuticals Limited. Last updated 18th June 2013
Accessed from eMC website February 26th 2015.
SPC Fosrenol oral powder, Shire Pharmaceuticals Limited. Last updated 3rd November 2012.
Accessed from eMC website February 26th 2015
Prices from Drug Tariff October 2015

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