Berkshire West Integrated Care System
Representing
Berkshire West Clinical Commisioning Group
Royal Berkshire NHS Foundation Trust
Berkshire Healthcare NHS Foundation Trust
Berkshire West Primary Care Alliance

Prescribing Guidelines

Prescribing arrangement for the management of patients transferring from ***Secondary Care to Primary Care***

Non-calcium based binders Sucroferric Oxyhydroxide for the treatment of hyperphosphataemia in adults with chronic kidney disease

APC PG [034]

For the latest information on interactions and adverse effects, always consult the latest version of the Summary of Product Characteristics (SPC), which can be found at: http://www.medicines.org.uk/

Approval and Authorisation

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Approved by	Job Title	Date
RBH Drugs and Therapeutics Committee	S Hussain, Chair	August 2018
BW Area Prescribing Committee	G Braham, Chair	November 2018

Change History

Version	Date	Author	Reason
v.1.0	July 2018	L Yap	New document

This prescribing guideline remains open to review considering any new evidence.

This guideline should only be viewed online and will no longer be valid if printed off or saved locally

Introduction

This prescribing guideline has been prepared to support healthcare professionals in the implementation of shared care management of patients who have been prescribed sucroferric oxyhydroxide for hyperphosphataemia in chronic kidney disease.

Sucroferric oxyhydroxide 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.

Patients with chronic renal failure are unable to excrete phosphate. A build up of phosphate enhances parathyroid activity and leads to calcification of arteries, thus significantly contributing to the excess cardiovascular morbidity in these patients. Adequate control of serum phosphate levels is therefore essential for prevention of vascular and cardiac calcification in patients with renal failure.

This document should be used alongside guidance published by the **National Institute for Health and Clinical Excellence** (CG157 March 2013 and ESNM51 January 2015). NICE recommends that if hypercalcaemia develops with use of calcium-based binders, it may be necessary to convert to a non-calcium containing phosphate binder, or to use a combination of both.

RBH renal department would use calcium acetate as 1st line phosphate binder. Calcium carbonate (Calcichew) may be used if patients prefer a chewable tablet. If serum calcium level is raised, sevelamer would be used as 2nd line. Lanthanum is used when patient requires more than 2.4g sevelamer three times a day to control serum phosphate level. Sucroferric oxyhydroxide is a 3rd line agent and will be used when patients can't tolerate all other phosphate binders.

Principles of shared care

This shared care agreement outlines suggested ways in which the responsibilities for managing the prescribing of sucroferric oxyhydroxide can be shared between the consultant 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 consultant. If the consultant asks the GP to prescribe this drug, the GP must reply to this request as soon as practicable confirming whether or not they are happy to do so.

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

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

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

CONSULTANT Responsibilities	
1	To assess the patient and establish the need for sucroferric oxyhydroxide.
2	Discuss with patient relevant information on use, timing of dose, side effects and need for monitoring of medication.
3	Initiate treatment. RBH will prescribe for 2 weeks.
4	Confirm shared care by letter with the patient's GP and include the shared care guideline.
5	Monitor response to treatment. All monitoring will be undertaken at the renal unit. The consultant will advise the GP on any dosage adjustment required.

General Practitioner Responsibilities	
1	Reply to the request for shared care as soon as possible and before patient's supply run out.
2	Prescribe sucroferric oxyhydroxide at the dose recommended.
3	Adjust the dose as advised by the renal unit.
4	Report to and seek advice from the renal unit on any aspect of patient care that is of concern and may affect treatment.
5	Be aware of potential drug interactions when initiating new drugs.

Patient's role (or that of carer)	
1	Report to the specialist or GP if he/she does not have a clear understanding of the treatment and to report any concerns
2	Attend appropriate consultant and GP appointments
3	To have any required monitoring/tests carried out at regular intervals, as appropriate
4	Report any adverse events to the GP or renal unit.

SUPPORTING INFORMATION

Dosage and administration

Control of serum phosphate level has been demonstrated at doses starting at 500mg three times a day. Serum phosphorus levels must be monitored and the dose of sucroferric oxyhydroxide up or down titrated in increments of 500 mg iron (1 tablet) per day every 4 weeks until an acceptable serum phosphorus level is reached (1.1 – 1.7 mmol/L), with regular monitoring afterwards. Maximum dose is 1000mg three times a day.

Sucroferric oxyhydroxide is available as tablets containing 500mg.

The tablets should be taken with food. Patients are not required to drink more fluid than they normally would. Tablets must be chewed and not swallowed whole; tablets may be crushed.

Contraindications

- Haemochromatosis and any other iron accumulation disorders

Special Warnings

- Caution use in patients with a recent history of peritonitis (within the last 3 months), significant gastric or hepatic disorders and patients with major gastrointestinal surgery as they were not included in clinical studies.
- Sucroferric oxyhydroxide contains sucrose. Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take this medicine. May be harmful to the teeth.
- Sucroferric oxyhydroxide contains starches. Patients with diabetes should take notice that one tablet of Velphoro is equivalent to approximately 1.4 g of carbohydrates (equivalent to 0.116 bread units).
- Sucroferric oxyhydroxide can cause discoloured (black) stool. Discoloured (black) stool may visually mask gastrointestinal bleeding

Pregnancy and breastfeeding

- No available clinical data from the use of sucroferric oxyhydroxide on exposed human pregnancies. Animal studies revealed no risk with respect to pregnancy, embryonic/foetal development, parturition or postnatal development.
- No available clinical data from the use of sucroferric oxyhydroxide in breast-feeding women. Since absorption of iron from sucroferric oxyhydro xide is minimal, excretion of iron in breast milk is unlikely.

Drug interactions

Interactions are theoretically possible with products known to interact with iron like alendronate, doxycycline and levothyroxine. These must be taken at least one hour before or two hours after sucroferric oxyhydroxide.

Side Effects

Most commonly reported side effects are gastrointestinal in nature, with the most commonly reported being diarrhoea and discoloured faeces. Other gastrointestinal side effects include: nausea, vomiting, abdominal pain, constipation, dyspepsia and flatulence. These occur early during treatment and generally abate with time with continued dosing.

This list is not exhaustive – the manufacturer's summary of product characteristics (SPC) and the most current edition of the British National Formulary (BNF) should be consulted for full information on contra-indications, warnings, side-effects and drug interactions.

Cost

NHS list price (BNF. Accessed via www.medicinescomplete.com on 21st Feb 2018)

500mg tablets	£179.00 per 90

Further Information

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Haemodialysis Lead Nurse	Angela Clarke
Renal Pharmacist	Lindsay Yap

Agreement to shared care, signed by Consultant's signature: _____ Consultant's name: _____ Date:	 GP's signature: _____ GP's name: _____ Date: