Effective Shared Care Agreement (ESCA)

Sodium Clodronate

ESCA: For the management of osteolytic lesions, bone pain and hypercalcaemia associated with multiple myeloma or breast cancer

AREAS OF RESPONSIBILITY FOR THE SHARING OF CARE

This shared care agreement outlines suggested ways in which the responsibilities for managing the prescribing of sodium clodronate for the management of osteolytic lesions, hypercalcaemia and bone pain associated with multiple myeloma or breast cancer can be shared between the specialist and general practitioner (GP). You are **invited** to participate however, if you do not feel confident to undertake this role, then you are 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.

Sharing of care assumes communication between the specialist, GP and patient. The intention to share care will be explained to the patient by the specialist initiating treatment. It is important that patients are consulted about treatment and are in agreement with it. Patients with osteolytic lesions, hypercalcaemia and bone pain associated with multiple myeloma or breast cancer are usually under regular specialist follow-up, which provides an opportunity to discuss drug therapy.

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

RESPONSIBILITIES and ROLES

Specialist responsibilities
1. Confirm the diagnosis of osteolytic lesions, hypercalcaemia and bone pain associated with multiple myeloma or breast cancer.
2. Discuss the potential benefits, treatment side effects, and possible drug interactions with the patient.
3. Provide specific advice in relation to osteonecrosis of the jaw, including consideration of need for dental examination and preventative dentistry prior to initiation.
4. Ask the GP whether he or she is willing to participate in shared care before initiating therapy so that appropriate follow on prescribing arrangements can be made.
5. Initiate treatment and stabilise dose of sodium clodronate (usually 4 to 8 weeks).
6. Review the patient's condition and monitor response to treatment regularly.
7. A written summary to be sent promptly to the GP i.e. within 10 working days of a hospital outpatient review or inpatient stay
8. Normally monitoring of biochemical and haematological parameters will be done by the specialist. Exceptionally a specialist may ask for the GP to monitor renal and hepatic function, white cell count, serum calcium and phosphate levels and explain what to do if results fall out of range.
9. Report serious adverse events to the MHRA.
10. Ensure clear backup arrangements exist for GPs, for advice and support (Please complete details below).

General Practitioner responsibilities						
1. Reply to the request for shared care as soon as practicable i.e. within 10 working days.						
2. Prescribe sodium clodronate at the dose recommended.						
3. In the patient's notes, using the appropriate Read Code listed below, denote that the patient is receiving treatment under a shared care agreement						
GP Prescribing System	**Read Code**	**Description**		**GP Prescribing System**	**Read Code**	**Description**
EMIS and Vision	8BM5.00	Shared care prescribing		SystmOne	XaB58	Shared care
4. Monitor patient's response to treatment; make dosage adjustments if agreed with specialist						
5. Report to and seek advice from the specialist or clinical nurse specialist on any aspect of patient care that is of concern to the GP, patient or carer and may affect treatment.						
6. Refer back to specialist if condition deteriorates.						
7. Report serious adverse events to specialist and MHRA.						
8. Stop treatment on advice of specialist.						

Patient's role
1. Report to the specialist, clinical nurse specialist or GP if he or she does not have a clear understanding of the treatment.
2. Share any concerns in relation to treatment with sodium clodronate with the specialist, clinical nurse specialist or GP.
3. Report any adverse effects to the specialist or GP whilst taking sodium clodronate.
4. Attend regular outpatient appointments with the specialist.

BACK-UP ADVICE AND SUPPORT

Contact details		Telephone No.	Email address:
Trust			
	Consultant:-		
	Specialist Nurse		

SUPPORTING INFORMATION

Indication	For the management of osteolytic lesions, hypercalcaemia and bone pain associated with skeletal metastases in patients with carcinoma of the breast or multiple myeloma.	
Dosage and Administration	A daily dose of 1600 mg should be taken as a single dose. When higher daily doses are used, the part of the dose exceeding 1600 mg should be taken separately (as a second dose) as recommended below. The single daily dose and the first dose of two should preferably be taken in the morning on an empty stomach together with a glass of water. The patient should then refrain from eating, drinking (other than plain water), and taking any other oral drugs for one hour. When twice daily dosing is used, the first dose should be taken as recommended above. The second dose should be taken between meals, more than two hours after and one hour before eating, drinking (other than plain water), or taking any other oral drugs. Clodronate should in no case be taken with milk, food or drugs containing calcium or other divalent cations because they impair the absorption of clodronate.	
Renal Impairment	Mild - Creatinine Clearance 50-80 ml/min	1600 mg daily (no dose reduction recommended)
	Moderate - Creatinine Clearance 30-<50 ml/min	1200 mg/daily
	Severe - Creatinine Clearance 10-<30 ml/min	800 mg/daily
Contra-indications / Special precautions	**Contraindication:-** Severe renal failure where creatinine clearance is below 10 ml/min Hypersensitivity to the active substance or to any of the excipients In patients receiving concomitant treatment with other bisphosphonates. Sodium clodronate is not recommended during pregnancy and in women of childbearing potential not using effective contraception Breast-feeding should be discontinued during treatment with sodium clodronate **Caution:-** Patients with renal insufficiency:- Adequate fluid intake must be maintained during clodronate treatment. Renal function with serum creatinine, serum calcium and phosphate levels should be monitored before and during treatment. Dental conditions and osteonecrosis of the jaw:- Osteonecrosis of the jaw has also been reported in patients with osteoporosis receiving oral bisphosphonates. A dental examination with appropriate preventive dentistry should be considered prior to treatment with bisphosphonates in patients with concomitant risk factors (e.g. cancer, chemotherapy, radiotherapy, corticosteroids, poor oral hygiene). While on treatment, these patients should avoid invasive dental procedures if possible. For patients who develop osteonecrosis of the jaw while on bisphosphonate therapy, dental surgery may exacerbate the condition. Atypical fractures of the femur:- Discontinuation of bisphosphonate therapy in patients suspected to have an atypical femur fracture should be considered pending evaluation of the patient, based on an individual benefit risk assessment. During bisphosphonate treatment patients should be advised to report any thigh, hip or groin pain and any patient presenting with such symptoms should be evaluated for an incomplete femur fracture Sodium clodronate is not recommended during pregnancy and in women of childbearing potential not using effective contraception Breast-feeding should be discontinued during treatment with sodium clodronate	
Side Effects	Common	Asymptomatic hypocalcemia, diarrhoea, nausea, vomiting
Monitoring	It is recommended that appropriate monitoring of hydration status and renal function with serum creatinine measurement be carried out during treatment. Serum calcium should be monitored periodically	
Drug Interactions	**Sodium Clodronate** has the following interaction information: Estramustine: sodium clodronate increases plasma concentration of estramustine Sodium Clodronate belongs to **Bisphosphonates** and will have the following interactions: Aminoglycosides: increased risk of hypocalcaemia when bisphosphonates given with aminoglycosides Antacids: absorption of bisphosphonates reduced by antacids **Note:** Antacids should preferably not be taken at the same time as other drugs since they may impair absorption Calcium Salts: absorption of bisphosphonates reduced by calcium salts **Note:***see also* Antacids Iron Salts: absorption of bisphosphonates reduced by *oral* iron salts	

References

SmPC Bonefos
Sodium clodronate BNF

I agree to participate in this shared care agreement for the treatment of the below named patient with sodium clodronate for the management of osteolytic lesions, hypercalcaemia and bone pain associated with multiple myeloma or breast cancer

General Practitioner
Name (please print)_____Signature _____Date_____

Hospital Specialist/Consultant
Name (please print)_____Signature_____Date_____

Patient's name	Date of birth	Sex	Home Address	Hospital Number
				NHS Number

Please keep a copy of this agreement for your own records and forward the original to the above named Consultant at: