Effective Shared Care Agreement (ESCA)

Ibandronic Acid 50 mg

ESCA: For the treatment of skeletal events in metastatic 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 ibandronic acid 50 mg for the prevention of skeletal events in metastatic 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 metastatic 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 breast cancer with bone metastases.
2. Discuss the potential benefits, treatment side effects, and possible drug interactions with the patient.
3. Discuss risk of osteonecrosis of the jaw with the patient and consider if a dental examination with appropriate preventative dentistry should be conducted prior to commencing treatment with ibandronic acid. (Risk factors include cancer, chemotherapy, radiotherapy, corticosteroids, poor oral hygiene).
4. Ensure that hypocalcaemia and other disturbances of bone and mineral metabolism are effectively treated before starting ibandronic acid therapy. Baseline monitoring of serum creatinine, urea, electrolytes (including calcium, phosphate and magnesium), LFTs, full blood count. Normally monitoring of biochemical and haematological parameters will be done by the specialist.
5. 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.
6. Do baseline monitoring prior to initiation of ibandronic acid 50 mg.
7. Initiate treatment and stabilise dose of ibandronic acid 50 mg.
8. Review the patient's condition and monitor response to treatment regularly.
9. A written summary to be sent promptly to the GP i.e. within 10 working days of a hospital outpatient review or inpatient stay.
10. Report serious adverse events to the MHRA.
11. 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 ibandronic acid 50 mg 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. Inform the specialist and GP of any other medication being taken, including over-the-counter products and of any current or recent dental treatment.
3. Share any concerns in relation to treatment with ibandronic acid 50 mg with the specialist, clinical nurse specialist or GP
4. Report any adverse effects to the specialist or GP whilst taking ibandronic acid 50 mg
5. Attend regular outpatient appointments with the specialist

BACK-UP ADVICE AND SUPPORT

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

Based on MTRAC template
Prepared by Satnaam Singh Nandra
Interface Lead Pharmacist
Birmingham CrossCity CCG

SUPPORTING INFORMATION

<table>
<tr><td>Indication</td><td colspan="2">For adults for the prevention of skeletal events (pathological fractures, bone complications requiring radiotherapy or surgery) in patients with breast cancer and bone metastases.</td></tr>
<tr><td>Dosage and Administration</td><td colspan="2">The recommended dose is one 50 mg tablet daily.

Tablets should be taken after an overnight fast (at least 6 hours) and before the first food or drink of the day.

Medicinal products and supplements (including calcium) should similarly be avoided prior to taking ibandronic acid 50 mg tablets.

Fasting should be continued for at least 30 minutes after taking the tablet. Water may be taken at any time during the course of ibandronic acid 50 mg treatment.

Water with a high concentration of calcium should not be used. If there is concern regarding potentially high levels of calcium in the tap water (hard water), it is advised to use bottled water with a low mineral content.

The tablets should be swallowed whole with a full glass of water (180 to 240 ml) while the patient is standing or sitting in an upright position.

Patients should not lie down for 60 minutes after taking ibandronic acid 50 mg

Patients should not chew, suck or crush the tablet because of a potential for oropharyngeal ulceration.

Water is the only drink that should be taken with ibandronic acid 50 mg</td></tr>
<tr><td rowspan="3">Renal Impairment</td><td>Mild
(CrCl ≥50 and <80 mL/min).</td><td>No dose adjustment is required</td></tr>
<tr><td>Moderate
(CrCl ≥30 and <50 mL/min)</td><td>A dosage adjustment to one 50 mg tablet every second day is recommended</td></tr>
<tr><td>Severe (CrCl <30 mL/min)</td><td>The recommended dose is one 50 mg tablet once weekly.</td></tr>
<tr><td>Hepatic impairment</td><td colspan="2">No dose adjustment is required</td></tr>
<tr><td>Contra-indications / Special precautions</td><td colspan="2">Contraindication:
Hypersensitivity to ibandronic acid or to any of the excipients listed
Hypocalcaemia
Abnormalities of the oesophagus which delay oesophageal emptying such as stricture or achalasia
Inability to stand or sit upright for at least 60 minutes
Pregnancy and breast-feeding - ibandronic acid should not be used in pregnancy or by women who are breast feeding.
Caution:
• Patients with disturbances of bone and mineral metabolism. Hypocalcaemia and other disturbances of bone and mineral metabolism should be effectively treated before starting.
• Ibandronic acid therapy. Adequate intake of calcium and vitamin D is important in all patients. Patients should receive supplemental calcium and/or vitamin D if dietary intake is inadequate.
Gastrointestinal irritation
• Orally administered bisphosphonates may cause local irritation of the upper gastrointestinal mucosa. Because of these possible irritant effects and a potential for worsening of the underlying disease, caution should be used when ibandronic acid is given to patients with active upper gastrointestinal problems (e.g. known Barrett's oesophagus, dysphagia, other oesophageal diseases, gastritis, duodenitis or ulcers).
• Adverse experiences such as oesophagitis, oesophageal ulcers and oesophageal erosions, in some cases severe and requiring hospitalization, rarely with bleeding or followed by oesophageal stricture or perforation, have been reported in patients receiving treatment with oral bisphosphonates. The risk of severe oesophageal adverse experiences appears to be greater in patients who do not comply with the dosing instruction and/or who continue to take oral bisphosphonates after developing symptoms suggestive of oesophageal irritation. Patients should pay particular attention and be able to comply with the dosing instructions.</td></tr>
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	• Physicians should be alert to any signs or symptoms signaling a possible oesophageal reaction and patients should be instructed to discontinue ibandronic acid and seek medical attention if they develop dysphagia, odynophagia, retrosternal pain or new or worsening heartburn. Acetylsalicylic acid and NSAIDs • Since acetylsalicylic acid, non steroidal anti inflammatory medicinal products (NSAIDs) and bisphosphonates are associated with gastrointestinal irritation, caution should be taken during concomitant administration. Osteonecrosis of the jaw • Osteonecrosis of the jaw, generally associated with tooth extraction and/or local infection (including osteomyelitis), has been reported in patients with cancer receiving treatment regimens including primarily intravenously administered bisphosphonates. Many of these patients were also receiving chemotherapy and corticosteroids. 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. For patients requiring dental procedures, there are no data available to suggest whether discontinuation of bisphosphonate treatment reduces the risk of osteonecrosis of the jaw. Clinical judgement of the treating physician should guide the management plan of each patient based on individual benefit/risk assessment. Atypical fractures of the femur • Atypical subtrochanteric and diaphyseal femoral fractures have been reported with bisphosphonate therapy, primarily in patients receiving long term treatment for osteoporosis. These transverse or short oblique fractures can occur anywhere along the femur from just below the lesser trochanter to just above the supracondylar flare. These fractures occur after minimal or no trauma and some patients experience thigh or groin pain, often associated with imaging features of stress fractures, weeks to months before presenting with a completed femoral fracture. Fractures are often bilateral; therefore the contralateral femur should be examined in bisphosphonate treated patients who have sustained a femoral shaft fracture. Poor healing of these fractures has also been reported. • 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. Renal function • Clinical studies have not shown any evidence of deterioration in renal function with long term ibandronic acid therapy. • Nevertheless, according to clinical assessment of the individual patient, it is recommended that renal function, serum calcium, phosphate and magnesium should be monitored in patients treated with ibandronic acid. Rare hereditary problems • Ibandronic acid tablets contain lactose and should not be administered to patients with rare hereditary problems of galactose intolerance, Lapp lactase deficiency or glucose galactose malabsorption. Patients with known hypersensitivity to other bisphosphonates Caution is to be taken in patients with known hypersensitivity to other bisphosphonates.
Side Effects	Common: Hypocalcaemia, oesophagitis, abdominal pain, dyspepsia, nausea, asthenia
Monitoring	Osteonecrosis of the jaw - dental examination Renal function Serum calcium, phosphate and magnesium Signs or symptoms signaling a possible oesophageal reaction

<table>
<tr><td>Drug Interactions</td><td></td></tr>
<tr><td></td><td>Ibandronic Acid has no specific interaction information.
Ibandronic Acid belongs to Bisphosphonates and will have the following interactions:
<table>
<tr><td>Aminoglycosides</td><td>increased risk of hypocalcaemia when bisphosphonates given with aminoglycosides</td></tr>
<tr><td>Antacids</td><td>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</td></tr>
<tr><td>Calcium Salts</td><td>absorption of bisphosphonates reduced by calcium salts
Note:see also Antacids</td></tr>
<tr><td>Iron Salts</td><td>absorption of bisphosphonates reduced by oral iron salts</td></tr>
</table></td></tr>
<tr><td>Medicinal product Food Interactions</td><td>Products containing calcium and other multivalent cations (such as aluminium, magnesium, iron), including milk and food, are likely to interfere with absorption of ibandronic acid tablets. Therefore, with such products, including food, intake must be delayed at least 30 minutes following oral administration.
Bioavailability was reduced by approximately 75% when ibandronic acid tablets were administered 2 hours after a standard meal. Therefore, it is recommended that the tablets should be taken after an overnight fast (at least 6 hours) and fasting should continue for at least 30 minutes after the dose has been taken.</td></tr>
<tr><td>Acetylsalicylic acid and NSAIDs</td><td>Since acetylsalicylic acid, nonsteroidal antiInflammatory medicinal products (NSAIDs) and bisphosphonates are associated with gastrointestinal irritation, caution should be taken during concomitant administration</td></tr>
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References

SmPC Bondronat
Ibandronic acid BNF

I agree to participate in this shared care agreement for the treatment of the below named patient with of ibandronic acid 50 mg for the prevention of skeletal events in metastatic 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: