Degarelix

ESCA: For the treatment of advanced hormone-dependent prostate 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 degarelix in prostate 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 prostate 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 prostate cancer histologically and/or radiologically
2. Discuss the potential benefits, treatment side effects, and possible drug interactions with the patient.
3. Ask the GP whether he or she is willing to participate in shared care before initiating therapy where possible so that appropriate follow on prescribing arrangements can be made
4. Do baseline monitoring of serum PSA, LFT's, U+E's and radiological staging (which may include NM bone scan/CT chest/abdomen/pelvis/ MRI spine/renal USS) prior to initiation of degarelix.
5. Administer initial loading dose of 240mgs as 2x120mgs injections in the lower anterior abdomen 6. Stabilise patient on 80mgs Degarelix for 2 months before requesting GP participates in shared care prescribing
7. Review the patient's condition and monitor response to treatment 3-6 monthly.
8. Send a written summary promptly to the GP i.e. within 10 working days of a hospital outpatient review or inpatient stay.
9. Report serious adverse events to the MHRA via Yellow Card Scheme https://yellowcard.mhra.gov.uk
10. Ensure clear backup arrangements exist for GPs, for advice and support (please complete contact details in appendix 1).

General Practitioner responsibilities						
1. Reply to the request for shared care as soon as practicable i.e. within 10 working days.						
2. Prescribe 80mgs degarelix every 28 days						
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. 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 or if condition deteriorates.						
5. Ensure the administration of degarelix injection is carried out by trained practice staff only and not by patients						
6. Report serious adverse events to specialist and MHRA via the Yellow Card Scheme https://yellowcard.mhra.gov.uk						
7. Stop treatment on the advice of specialist.						

Patient's role
1. Report to the specialist, clinical nurse specialist or GP if he does not have a clear understanding of the treatment.
2. Attend regularly for required blood tests and out-patient appointment clinic reviews
3. Share any concerns in relation to treatment with degarelix with the specialist, clinical nurse specialist or GP.
4. Report any adverse effects to the specialist or GP whilst receiving degarelix.

Please enter Specialists' contact details and patient specific information in Appendix 1

SUPPORTING INFORMATION

NICE TA 404	Degarelix is recommended as an option for treating advanced hormone-dependent prostate cancer in men with signs or symptoms of spinal metastases, only if the commissioner can achieve at least the same discounted drug cost as that available to the NHS in June 2016.		
Licensed indication	Treatment of adult male patients with advanced hormone-dependent prostate cancer.		
Dosage and Administration	Starting dose	To be prescribed and administered by secondary care.	240mg administered as two subcutaneous injections of 120 mg each.
	Initial maintenance dose (for 2 months)	To be prescribed and administered by secondary care.	80mg administered monthly as one subcutaneous injection every 28 days
	Maintenance dose	To be prescribed and administered **monthly** by primary care.	80mg administered monthly as one subcutaneous injection.
	The first maintenance dose should be given one month after the starting dose in secondary care If the patient misses his degarelix injection by more than 2 weeks, he should be given the initiation dose of 240mg degarelix (as two subcutaneous injections of 120mg each) and then follow the monthly 80mg degarelix schedule thereafter. PSA should be measured. Inform secondary care specialist team		
	• **NOTE: THE VIALS SHOULD NOT BE SHAKEN** • **Degarelix is for subcutaneous use ONLY.** • The instructions for reconstitution must be followed carefully – please see packaging leaflet. • The reconstituted solution should be a clear liquid, free of undissolved matter. • Degarelix is administered in the abdominal region. The injection site should vary periodically. Injections should be given in areas where the patient will not be exposed to pressure e.g. not close to waistband or belt and not close to the ribs. • Administration of other concentrations is not recommended because the gel depot formation is influenced by the concentration. • www.ferringukhcp.co.uk/urology/firmagon -training video on-line		
Special populations: Elderly, renal or hepatic impairment.	No modification is required for mild – moderate renal or hepatic impairment. Consultant urologists/oncologists will ensure patients with more severe hepatic or renal impairment are stable on treatment before sharing care.		
Contra-indications	Hypersensitivity to the active substance or to any of the excipients.		
Special precautions			
Side Effects	Very common	Hot flush*, injection site discomfort and or redness	
	Common	Anaemia*, weight increase*, insomnia, dizziness, headache, diarrhoea, nausea, increased liver transaminases, hyperhidrosis (incl. night sweats)*, rash, musculoskeletal pain and discomfort*, gynaecomastia*, testicular atrophy*, erectile dysfunction*, chills, pyrexia, fatigue*, Influenza-like illness. *known physiological consequence of testosterone suppression	

<table>
<tr><td colspan="4">Monitoring</td></tr>
<tr><td>Pre-treatment (Baseline) monitoring</td><td colspan="3">Specialists please complete the information in table below:
<table><tr><th>Parameter</th><th>Baseline results</th></tr><tr><td>Serum prostate specific antigen (PSA) levels- ng/mL</td><td></td></tr><tr><td>Liver function tests including Alk Phos</td><td></td></tr><tr><td>Full blood count</td><td></td></tr><tr><td>Bone density (Bone Mass Density) (if applicable)</td><td></td></tr></table></td></tr>
<tr><td>On- going monitoring By secondary care</td><td><u>Parameter</u></td><td colspan="2"><u>Frequency (once stable)</u></td></tr>
<tr><td></td><td>Serum PSA</td><td colspan="2">3-6 monthly</td></tr>
<tr><td></td><td>U+Es</td><td colspan="2">Annually</td></tr>
<tr><td></td><td>Bone profile</td><td colspan="2">Annually</td></tr>
<tr><td></td><td>Liver function tests</td><td colspan="2">annually</td></tr>
<tr><td></td><td>Full blood count</td><td colspan="2">Annually</td></tr>
<tr><td>Actions to be taken if out of range:</td><td><u>Parameter</u></td><td><u>Reason for review</u></td><td><u>Follow up action</u></td></tr>
<tr><td></td><td>Prostate specific antigen (PSA) levels</td><td>Raised above threshold or 50% rise in baseline PSA in 6 months in 2 consecutive measurements</td><td>Specialist team for re-assessment</td></tr>
<tr><td></td><td>Liver function - in patients with known or suspected hepatic disorder</td><td>Raised ALT and AST</td><td>Specialist team for re-assessment</td></tr>
<tr><td></td><td>Lower urinary tract symptoms</td><td>Deterioration</td><td>Specialist team for re-assessment</td></tr>
<tr><td></td><td>Bone pain</td><td></td><td>Specialist team for re-assessment</td></tr>
<tr><td>Re-referral to specialist team</td><td>If patient develops the following symptoms:
• Lower limb neurology
• Suspicion of spinal cord compression</td><td colspan="2">Contact the Urology/Oncology on call team on the same day by telephone (see contact details below).</td></tr>
<tr><td>Drug Interactions (significant interaction as outlined in BNF, please see BNF and SPC for more detail)</td><td colspan="3">No formal drug-drug interaction studies have been performed.

Since androgen deprivation treatment may prolong the QTc interval, the concomitant use of degarelix with medicinal products known to prolong the QTc interval or medicinal products able to induce torsades de pointes such as class IA (e.g. quinidine, disopyramide) or class III (e.g. amiodarone, sotalol, dofetilide, ibutilide) antiarrhythmic medicinal products, methadone, moxifloxacin, antipsychotics, etc. should be carefully evaluated.</td></tr>
</table>

References

SmPC Firmagon® Injection
NICE TA404 - Degarelix for treating advanced hormone-dependent prostate cancer
NICE CG75 - Metastatic spinal cord compression in adults: risk assessment, diagnosis and management

Appendix 1:

Effective Shared Care Agreement (ESCA)

Degarelix

ESCA: For the treatment of advanced hormone-dependent prostate cancer

Please refer to BSSE APC formulary website for complete document.

BACK-UP ADVICE AND SUPPORT (To be completed by Specialist team)

Trust	Contact details	Telephone No.	Email address:
	Consultant :-		
	Specialist Nurse:-		
	On-call Oncology team :-		

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

Hospital Specialist/Consultant
Name (please print)_____Signature_____Date_____

To be completed by the General Practitioner:

I agree to participate in this shared care agreement for the treatment of the above named patient with degarelix in prostate cancer.

General Practitioner
Name (please print)_____Signature _____Date_____

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

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
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