

SHARED CARE GUIDELINE

For

Degarelix 80mg SC Injection – Prostate Cancer

Implementation Date: February 1st 2014

Review Date: August 2015

This guidance has been prepared and approved for use in South Tyneside in consultation with Primary and Secondary Care Trusts, primary care medicines management committees and Local Medical Committees.

The guideline sets out the details of the transfer of prescribing and respective responsibilities of GPs and specialist services within shared care prescribing arrangements. It is intended to provide sufficient information to allow GPs to prescribe these treatments within a shared care setting.

Further copies are available from

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Approved by:

Committee	Date
South Tyneside Medicines Management Committee	August 13th 2013

Name of drug:	Degarelix	Form and strength:	80mg SC Injection
Brand name:	Firmagon	BNF Code:	8.3.4.2
Conditions(s) to be treated Module 2 - Patients with prostate cancer suitable for androgen depletion therapy who remain under the care of the Urologist and may in addition have more complex treatment regimes. Only to be used for: For first line treatment of advanced hormone-dependent prostate cancer at least one of the following: PSA > 50ng/l at presentation, Urethral Obstruction, Symptoms of Spinal Cord Compression		Aim of treatment Metastatic prostate cancer is commonly responsive to hormonal treatment designed to deprive the cancer of androgen Provision of treatment in primary care will improve the patient experience by providing care closer to home and will contribute to the transfer of activity out of secondary care.	
Excluded patients		Unstable disease state	
Eligibility criteria for shared care		Following dose and drug stabilisation for at least 1 month	
Initiation		Initiation of treatment will take place in secondary care at a different dose	
Duration of treatment		As agreed with secondary care	
Usual Maintenance Dose		80mg every 4 weeks by subcutaneous injection into anterior	

	abdominal wall or as directed by secondary care physician
Usual Dose Range	80mg
Maximum Dose	80mg maintenance dose
Available Strengths (Colours)	80mg and 120mg doses are available. 120mg is for use as a loading dose only which is not to be given in primary care
Preparations	Supplied as an 80mg vial containing powder for reconstitution with a supplied solvent, syringe & needles
Administration	<ol style="list-style-type: none"> 1. Check the patient's medication sheet to ensure degaralix dose and frequency is written and signed by the prescribing doctor. Check no previous reaction to degaralix. 2. Explain procedure to the patient. 3. Obtain informed consent. 4. Ask the patient to lie in a comfortable position with the upper part of the body slightly raised. If thin ask the patient to sit forward. 5. Wash hands and apply non-sterile gloves. 6. Do not shake the vials 7. Check the product is in-date and has not been tampered with 8. Remove the cover from the vial adapter pack and attach the adapters to both the solvent and the powder vial by pressing the adapter down until the spike pushes through the rubber stopper and the adapter snap in place. 9. Remove the cover from the syringe pack and attach the syringe to the solvent vial by screwing it on to the adapter. 10. Turn the vial upside down and draw up precisely 4.2ml of the provided solvent into the syringe. Detach the syringe from the adapter and discard the vial containing the excess solvent. 11. Attach the syringe to the powder vial by screwing it on the adapter. Transfer the solvent to the powder vial. 12. With the syringe still attached to the adapter, swirl very gently until the liquid looks clear and without undissolved powder or particles. In case the powder adheres to the vial over the liquid surface, the vial over the liquid surface, the vial can be tilted slightly. Avoid shaking to prevent foam formation. 13. A ring of small air bubbles on the surface of the liquid is acceptable. The reconstitution procedure may take, in some cases, up to 15 minutes, but usually takes a few minutes 14. Turn the vial upside down and, holding it vertically, draw 4.0ml of solution into the syringe for injection. Always make sure to withdraw the precise volume. It may be necessary to tilt the vial slightly. 15. Detach the syringe from the vial adapter and attach the 25g injection needle. Carefully, expel any air bubbles from the syringe 16. Grasp the skin of the patient's abdomen to elevate the subcutaneous tissue. Inject the 4ml (80mg) at an angle of at least 45 degrees. The injection should be given immediately after reconstitution. 17. Degaralix must only be given sub-cutaneously. Injection by other routes may be harmful. Blood should not be seen in the syringe after administration.
Cost 28 days (Drug Tariff)	£ 129.37 (list price) which NHS SOTW will then be able to reclaim part of the cost to make the cost the same as Zoladex
Adverse effects	<i>Common:</i> nausea; dizziness, headache, drowsiness, insomnia,

Incidence and actions to be taken	<p>asthenia; influenza-like symptoms; hot flushes, sweating (including night sweats), weight gain; injection-site reactions; <i>less commonly</i> diarrhoea, vomiting, abdominal discomfort, dry mouth, constipation, anorexia, atrio-ventricular block, QT-interval prolongation, fainting, hypertension, hypersensitivity reactions, depression, anxiety, oedema, gynaecomastia, micturition urgency, renal impairment, sexual dysfunction, pelvic pain, prostatitis, testicular pain, anaemia, musculoskeletal pain, tinnitus, urticaria, alopecia, and rash</p> <p>Contact urologist by telephone or letter for clinical review if the patient suffers a serious reaction.</p>	
Contra-indications	Known hypersensitivity to the product	
Renal impairment and liver disease	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.	
Pregnancy and breast feeding	Not applicable – treatment only for men.	
Monitoring	<p>Monthly appointments to:</p> <ul style="list-style-type: none"> • Administer injections. • Urologist responsible for monitoring patients. 	
Responsibilities	Consultant	<p>Complete section 1 of shared care request form</p> <p>Continue to monitor patient</p>
	G.P.	<p>Administration of degaralix injections</p> <p>Complete proforma to notify secondary care that injection has been given</p> <p>See service specification for full details</p> <p>Monitor PSA levels as directed by secondary care in accordance with service specification</p>
Communications	Consultant	Notification of patients suitable for shared care
	G.P.	<p>Acceptance of patient for shared care</p> <p>Notification of injections given</p>
Re- referral criteria	<p>Patients will remain under the care of the urology team who will review patients at least 3 monthly. If the patient develops any of the following symptoms, contact the named clinician in the urology team:</p> <ul style="list-style-type: none"> • Rising PSA (ie 50% rise in baseline PSA in 6 months in 2 consecutive measurements) • Deterioration in lower urinary tract symptoms • Bone pain <p>If patients develop the following symptoms:</p> <ul style="list-style-type: none"> • Lower limb neurology • Suspicion of spinal cord compression <p>Contact the Urology on call team on the same day by Telephone to arrange immediate admission at:- Freeman Hospital (for Gateshead)</p>	

	<p>Sunderland Royal Hospital (for Sunderland)</p> <p>Urgent Phone Call for same day referrals : 0191 5656257 (Sunderland Royal Hospital switchboard) 0191 2336161 (Freeman Hospital switchboard) and ask to speak to Urology on call team</p>
Contact details	<p>In the first instance advice on patient care can be obtained from:</p> <p>For South Tyneside: On call Urology oncology specialist nurse; 0191 4041000 (ext 2236)</p> <p>Alternatively, where a patient has been primarily receiving treatment at one of the following hospitals, and South Tyneside have not been able to offer the information required, patient information can be received from:-</p> <p>For Sunderland: On call Urologist, Sunderland Royal Hospital; 0191 5656256 (Sunderland Royal Hospital switchboard - ask to speak to on call Urologist)</p> <p>For Gateshead: Specialist Nurse Practitioner or Urology Nurse Practitioners Telephone 0191 4452217/2829 or 0191 4820000 and bleep urology nurse</p>
Agreed Date August 13th 2013	Expiry date August 2015