Frimley Health Area Prescribing Committee

Frimley Health NHS Foundation Trust
North East Hampshire and Farnham CCG
Windsor, Ascot and Maidenhead CCG, Bracknell and Ascot CCG & Slough CCG
Surrey Heath CCG

Amber (without shared care) –information sheet	
Name of medicine	Degarelix (Firmagon®)
Indication	Advanced hormone-dependent prostate cancer in adults males, restricted to those patients with severe symptoms including bony metastases.
Author(s):	Pharmacy and Urology department, Frimley Health
Date ratified by Frimley Health ICS Medicines Optimisation Board	March 2021
Review Date	March 2024

Degaralix has been reclassified as an Amber without Shared Care Medicine; these can be prescribed in primary care, on specialist advice without the need for a formal shared care agreement.
This **AMBER** without shared care information sheet sets out the patient pathway relating to this medicine and any information not available in the British National Formulary and manufacturer's Summary of Product Characteristics. Prescribing must be carried out with reference to those publications whenever appropriate.

Roles and Responsibilities

Consultant / Specialist

- Diagnosis of condition ensuring patients fit criteria for use,and initiation of treatment,
- Prescribe and administer the **starting dose** of **240mg subcutaneously**
- Undertake baseline monitoring
- Monitor patient's initial reaction to, and progress on, the drug.
- Ensure patient continues to receive the drug - liaise with the GP to request ongoing prescription and administration of the drug
- Provide GP with diagnosis, relevant clinical information and baseline results, treatment to date and treatment plan, duration of treatment before consultant review.
- Continue to monitor and supervise the patient according to this protocol, while the patient remains on this drug, and agree to review the patient promptly if contacted by the GP
- Provide GP with details of outpatient consultations in a timely manner or inform GP if the patient does not attend appointment.
- Provide GP with advice on when to stop the drug.
- Advise diabetic patients on potential effect on disease management and any additional monitoring required.
- Provide patient with relevant drug information to enable informed consent to therapy and understanding of potential side effects and appropriate action. Advise on side effects including that fatigue and dizziness care common adverse reactions that might influence the ability to drive and use machines.

Primary Care Prescriber

- Continue further prescriptions and administration of **maintenance dose** of degarelix **80mg subcutaneously** after initiation dose by secondary care and continue monthly unless advised to stop
- Monitor the patients overall health and well being and observing patient for evidence of adverse drug reactions and consult with secondary care clinician if necessary.
- Measure Blood tests (Serum PSA+/- bone profile, U+E's, LFTs, FBC) at intervals as specified by secondary care.
- Undertake more frequent tests if there is evidence of clinical deterioration, abnormal results or other risk factors. Contact consultant team for advice on monitoring in these circumstances.
- Patients should be maintained on degarelix until advise to stop or change to an alternative treatment, by specialist.

Patient Relatives & Carers

- Ask the specialist or GP for information if they do not have a clear understanding of the treatment.

- Attend GP practice for administration of degarelix
- Attend hospital and GP clinic appointments
- Read the patient information leaflet regarding the medication and report any side effects or concerns they have to the specialist or GP.

Key information on the medicine
Please refer to the current edition of the British National Formulary (BNF), available at https://bnf.nice.org.uk/ and Summary of Product Characteristics (SPC), available at www.medicines.org.uk for detailed product and prescribing information and specific guidance.

Background to disease and use of medicine for the given indication
Degarelix is a gonadotrphin-releasing hormone (GnRH) antagonist. It is licensed for treatment of adult male patients with advanced hormone-dependent prostate cancer. Unlike LHRH agonists, GnRH antagonists do not produce a LH surge at the start of treatment, there is no initial testosterone surge or tumour stimulation and therefore no potential for symptomatic flares. Patients therefore do not require concurrent treatment with anti-androgens when commencing therapy.

Indication
Degarelix is indicated for patients with advanced hormone dependent prostate cancer in whom rapid lowering of testosterone is required and in whom an initial tumour flare would be of significant clinical importance which precludes the patient from receiving an LHRH agonist. It should only be used as per NICE TA404 as an option in patients with spinal metastases.

Dosage and Administration
Refer to current Summary of Product Characteristics (SPC): www.medicines.org.uk

Cautions, contraindications, Drug interactions
Refer to current Summary of Product Characteristics (SPC): www.medicines.org.uk

Monitoring

Monitoring requirements : frequency - as recommended by the specialist	Responsible clinician
Pre-treatment: • Serum PSA • U&Es, bone profile, LFTs, FBC	Specialist Clinician
Maintenance: • Serum PSA • HBa1C (for diabetic patients only)	GP

Abnormal results – Actions to be taken.
Contact consultant –via advice and guidance.

Adverse effects and action to be taken (if appropriate) - Refer to current Summary of Product Characteristics (SPC): www.medicines.org.uk

The patient should be advised to report any of the following symptoms to their GP without delay and be referred back to secondary care:

- Deterioration in lower urinary symptoms
- Bone pain

Patients who have the following symptoms should be re-referred on the same day:
- Lower limb neurology
- Suspicion of spinal cord compression