Specialist Initiated Drugs

Prescribing Information Sheet February 2015

Degarelix (Firmagon®) - Advanced hormone-dependent prostate cancer

Formulary Status

Degarelix for the treatment of advanced hormone-dependent prostate cancer should be initiated by a specialist who will prescribe the initial supply.

The first dose of 240mg will be administered in Secondary care. Subsequent monthly SC injections of 80mg will be arranged by the GP and given in primary care.

The responsibility for stopping treatment due to lack of effect or side effects remains with the specialist

Full prescribing guidance – Summary of Product Characteristics www.emc.medicines.org.uk

Indication and Dosage

Indication- Degarelix is a gonadotrophin releasing hormone (GnRH) antagonist indicated for the treatment of adult male patients with advanced hormone-dependant prostate cancer. Degarelix will be prescribed for patients requiring a rapid lowering of testosterone presenting with symptoms such as:
Impending spinal cord compression (as per NICE CG 75)
Significant cardiac history
Renal failure due to ureteric obstruction

Presentation- 80mg and 120mg powder and solvent for solution for injection. After reconstitution, each ml of solution contains 20 mg of degarelix

Dosage and Administration –
Starting dose (to be prescribed & administered by secondary care)
 240mg administered as two subcutaneous injections of 120mg each
Maintenance dose (to be prescribed & administered in primary care)
 80mg monthly administered as one subcutaneous injection starting one month after the starting dose & continued monthly indefinitely

MUST BE GIVEN SUBCUTANEOUSLY; INJECTION BY OTHER ROUTES MAY BE HARMFUL

Approved by: East Kent Prescribing Group *(Representing Ashford CCG, Canterbury and Coastal CCG, South Kent Coast CCG and Thanet CCG)*
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Renal and hepatic impairment - There is no need to adjust the dose for the elderly or in patients with mild or moderate liver or kidney function impairment. Degarelix has not been studied in patients with severe renal or hepatic impairment and caution is therefore warranted.

Monitoring
Baseline – Specialist
Serum PSA
Full blood count
U&E's and LFT's & Bone profile

Every 6 months – GP
PSA

Missed dose by more than 2 weeks
PSA

Action to be taken
Patients should be referred back to secondary care if they have any one of the following symptoms:
PSA above threshold
Deterioration in lower urinary tract 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

Special warnings, precautions for use and adverse effects (consult SPC for full list)

Contraindications

Hypersensitivity to the active substance or to any of the excipients

Cautions
Glucose tolerance

A reduction in glucose tolerance has been observed in men who have had orchiectomy or who have been treated with a GnRH agonist. Development or aggravation of diabetes may occur; therefore diabetic patients may require more frequent monitoring of blood glucose when receiving androgen deprivation therapy. The effect of degarelix on insulin and glucose levels has not been studied.

Summary of the safety profile

The most commonly observed adverse reactions during degarelix therapy in the confirmatory phase III study (N=409) were due to the expected physiological effects of testosterone suppression, including hot flushes and weight increase (reported in 25% and 7%, respectively, of patients receiving treatment for one year), or injection site adverse reactions. Transient chills, fever or influenza like illness were reported to occur hours after dosing (in 3%, 2% and 1% of patients, respectively).

The injection site adverse reactions reported were mainly pain and erythema, reported in 28% and 17% of patients, respectively, less frequently reported were swelling (6%), induration (4%) and nodule (3%). These events occurred primarily with the starting dose whereas during maintenance therapy with the 80 mg dose, the incidence of these events pr 100 injections was: 3 for pain and <1 for erythema, swelling, nodule and induration. The reported events were mostly transient, of mild to moderate intensity and led to very few discontinuations (<1%).

Drug Interactions
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 (see section 4.4).
Degarelix is not a substrate for the human CYP450 system and has not been shown to induce or inhibit CYP1A2, CYP2C8, CYP2C9, CYP2C19, CYP2D6, CYP2E1, or CYP3A4/5 to any great extent in vitro. Therefore, clinically significant pharmacokinetic drug-drug interactions in metabolism related to these isoenzymes are unlikely.

Supply, storage and reconstitution instructions
Degarelix should not be mixed with other medicinal products. The vials should not be shaken. See SPC for instructions on reconstitution & administration

Storage Conditions after reconstitution
Chemical and physical in-use stability has been demonstrated for 2 hours at 25°C. From a microbiological point of view, unless the method of reconstitution precludes the risk of microbial contamination, the product should be used immediately. If not used immediately, in-use storage times and conditions are the responsibility of the user

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References

Summary of Product Characteristics**-** Firmagon® 80mg &120mg injection. Ferring Pharma Ltd. Last updated 18 Dec 2013 www.emc.medicines.org.uk

NICE CG 75 Metastatic spinal cord compression: Diagnosis and management of adults at risk of and with metastatic spinal cord compression. November 2008 www.nice.org.uk

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