# DEGARELIX (Firmagon)
# For the treatment of Prostate Cancer

***DOCUMENT TO BE SCANNED INTO ELECTRONIC RECORDS AS AND FILED IN NOTES***

**Patient Name :** **Date of Birth:** **NHS No:**

**Name of Referring Consultant:** **Contact number:**

## INTRODUCTION – Indication and Licensing

Degarelix (Firmagon®) is a gonadotrophin-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.
Degarelix is indicated for patients with advanced hormone dependent prostate cancer & spinal metastases in whom a rapid lowering of testosterone is required and in whom an initial tumour flare would be of significant clinical importance that precludes the patient from receiving an LHRH agonist.
Degarelix will be prescribed for patients who present with signs or symptoms of spinal cord compression or of cauda equina compression (as per NICE TAG 404).

## PATIENT PATHWAY

| Clinical Speciality / Indication | Prescribing Initiated by | Prescribing Continued by *(detail when suitable for transfer to occur)* | Monitored by *(detail when suitable for transfer to occur IF APPROPRIATE)* | Duration of treatment |
|---|---|---|---|---|
| | | | | |
| Uro-oncology patients with advanced hormone dependent prostate cancer in whom a rapid lowering of testosterone is required and in whom an initial tumour flare would be of significant clinical importance that precludes the patient from receiving an LHRH agonist | Specialist urologist or oncologist in uro-oncology outpatient clinics at BHR Hospitals NHS Trust.<br>Patients will receive an initial first month course of Degarelix from the hospital.<br>Patients who demonstrate an improvement will be continued on Degarelix by the GP in accordance with this SCG. | GP following first month of treatment by the hospital. | Baseline monitoring will be undertaken by the specialist for the first month of treatment after which monitoring will be undertaken as follows:<br><br><u>Baseline – specialist</u><br>Serum PSA<br>U&Es<br>Bone profile<br>Liver profile<br>Full blood count<br><br><u>Follow-up – by specialist</u><br>PSA 3-6 monthly | |

Patient selection criteria:

Shared care is appropriate where it provides the optimum treatment option for the patient. Prescribing responsibility will be transferred when the patient's condition is stable and when it is agreed by the consultant and the GP.

## ORAL DOSE AND ADMINISTRATION

Initiation dose (administered by specialist in secondary care):
240mg (administered as two injections of 120mg each) by subcutaneous injection.

Maintenance dose (administered by GP in primary care) to start 4 weeks after initiation dose:
80mg by subcutaneous injection every 4 weeks.

## MONITORING STANDARDS FOR MEDICATION AT BHRUniversity Hospitals NHS Trust

Note: be clear about what needs monitoring, normal parameters, how often and by whom. What results warrant referral back to the hospital team

| | |
|---|---|
| **Parameter** | PSA |
| **Target level** | Not applicable |
| **Frequency of monitoring** | Baseline then 3-6 monthly |
| **Action** | Patients should be referred back to secondary care if they have any of the following symptoms:<br>Deterioration in lower urinary tract symptoms<br>Bone pain<br>Lower limb neurology (refer to A&E for same day review)<br>Suspicion of spinal cord compression (refer to A&E for same day review) |

## *KEY ADVERSE EFFECTS & ACTIONS*

| **Adverse effects** | **Symptoms/signs** *(specify what would prompt action)* | **Actions (***what action should the GP take if identified in primary care)* |
|---|---|---|
| Physiological consequence of testosterone suppression (common) | Gynaecomastia, testicular atrophy, erectile dysfunction, decreased libido, hyperhidrosis (incl. night sweats), fatigue, hot flush, weight increase, anaemia. | Specialist review of treatment if patient intolerant of adverse effects. |
| Cardiac disorders (uncommon) | Cardiac arrhythmia (incl. atrial fibrillation), palpitations, QT prolongation. | Benefit/risk ratio must be appraised and documented in patients with a history of a corrected QT interval over 450 msec, a history of or risk factors for torsades de pointes and in patients receiving concomitant medicinal products that might prolong the QT interval. |
| Hepatobiliary disorders (common) | Liver transaminases increased. | Monitoring of liver function in patients with known or suspected hepatic disorder is advised during treatment. Stop treatment if patient intolerant of adverse effects. |
| Metabolism and nutrition disorders (uncommon) | Hyperglycemia/diabetes mellitus, cholesterol increased, weight decreased, appetite decreased, changes in blood calcium. | Diabetic patients may require more frequent monitoring of blood glucose |

**This only lists the key important ADRs-For comprehensive information on cautions, contra-indications and interactions, please refer to the current British National Formulary and Summary of Product Characteristics.**

**Detail any important cautions**

## *PREGNANCY AND BREAST FEEDING*

Not applicable – use in men only

## SHARED CARE

**Shared care guideline***:* is a document which provides information allowing patients to be managed safely by primary care, secondary care and across the interface. It assumes a partnership and an agreement between a hospital specialist, GP and the patient and also sets out responsibilities for each party. The intention to shared care should be explained to the patient and accepted by them. Patients are under regular follow-up and this provides an opportunity to discuss drug therapy. Intrinsic in the shared care agreement is that the prescribing doctor should be appropriately supported by a system of communication and cooperation in the management of patients. The doctor who prescribes the medicine has the clinical responsibility for the drug and the consequence of its use**.**

### Consultant

1. Ensure that the patient/carer is an informed recipient in therapy.
2. Ensure that patients understand their treatment regimen and any monitoring or follow up that is required (using advocacy if appropriate). Issue any local patient information leaflets where appropriate.
3. Ensure baseline investigations are normal before commencing treatment.
4. Initiate treatment and prescribe until the GP formally agrees to share care (as a minimum, supply the first month of treatment or until patient is stabilised).
5. Send a letter to the GP requesting shared care for this patient.
6. Clinical and laboratory supervision of the patient by blood monitoring and routine clinic follow-up on a regular basis.
7. Send a letter/results notification to the GP after each clinic attendance ensuring current dose, most recent blood results and frequency of monitoring are stated (unless otherwise covered by letter eg from Rheumatology Clinical Nurse Specialist or Pharmacy Drug Monitoring Service).
8. Where the GP is not performing the phlebotomy, the blood test form MUST be annotated to request that blood results are also copied to the GP
9. Evaluation of any reported adverse effects by GP or patient.
10. Advise GP on review, duration or discontinuation of treatment where necessary. Where urgent action is required following tests the hospital team will telephone the patient and inform GP.
11. Inform GP of patients who do not attend clinic appointments.
12. Ensure that backup advice is available at all times.
13. Ensure that the patient has received a flu vaccine prior to commencing treatment that is likely to cause immunosuppression. Document this in the patient notes and inform the GP it has been given

### General Practitioner

1. Reinforce the patient's understanding of the nature, effect and potential side effects of the drug before prescribing it as part of the shared care programme and contact the specialist for clarification where appropriate.
2. Monitor patient's overall health and well-being.
3. Report any adverse events to the consultant, where appropriate.
4. Report any adverse events to the CSM, where appropriate.
5. Help in monitoring the progression of disease
6. Maintain a patient held monitoring booklet where used
7. Prescribe the drug treatment as described.

### PCT

1. To provide feedback to trusts via Trust Medicines Committee.
2. To support GPs to make the decision whether or not to accept clinical responsibility for prescribing.
3. To support trusts in resolving issues that may arise as a result of shared care.

### Patient/ Carer

1. Report any adverse effects to their GP and/or specialist
2. Ensure they have a clear understanding of their treatment.
3. Report any changes in disease symptoms to GP and/or specialist
4. Alert GP and/or specialist of any changes of circumstance which could affect management of disease e.g. plans for pregnancy
5. Take/ administer the medication as prescribed
6. Undertake any monitoring as requested by the GP and/or specialist

**Costs**

| Drug Product | Cost per month in primary care |
|---|---|
| Degarelix (Firmagon) | (Initial dose £260 discounted to £176 to be administered in secondary care)<br>Maintenance dose £129.37 discounted to £89 |

Based on BNF edition November 2014 & discount as agreed by NICE June 2016

## *RESOURCES AVAILABLE*

NICE Clinical Guideline 75: Metastatic spinal cord compression: Diagnosis and management of adults at risk of and with metastatic spinal cord compression www.nice.org.uk
NICE Technology Appraisal 352: Prostate cancer (advanced, hormone dependent) - degarelix depot www.nice.org.uk
NICE Technology Appraisal 404 : https://www.nice.org.uk/guidance/ta404

| BHR University Hospitals NHS Trust | |
|---|---|
| Consultant via switchboard<br><br>Registrar on-call out of hours | Aircall via switchboard<br><br>Aircall via switchboard |
| Clinical Nurse Specialist (where appropriate) | Aircall via switchboard |
| Drug Monitoring Clinic Pharmacist (where appropriate) | |
| NHS Prescribing Team | To confirm new number |

## References

List key references used (e.g. NICE, published papers)

**Refer to the NHS Barking and Dagenham, Havering and Redbridge CCG website to obtain the latest version of this guideline**

*Template approved by Area Prescribing Committee (APC) on……2011. Guideline written by……on …….. Approved by APC on …… Review date: .....(2 years).*

# Degarelix (Firmagon®)

## SHARED CARE AGREEMENT LETTER

Name of GP ……..… Address …….
……...
…….……
..……..…

Dear GP

Re: Patient's Name……..……

Date of Birth…….……

Hospital Number……..…….

Indication for …….……

Route……(Oral/Intramuscular/Subcutaneous)- DELETE AS APPROPRIATE

Dose…….mg per month

Enclosed is a copy of the shared care guidelines for Degarelix (Firmagon®) to be retained in the patient's notes.
Should you agree to shared care, we will send a letter containing the details of the patient's treatment plan, the dose to be prescribed and all relevant blood results.

Please sign below and return this letter to the Hospital Specialist if you agree to the shared care arrangements for this patient.

Many thanks

| Hospital Specialist | GP |
|---|---|
| Signature……... | Signature……... |
| Name ……..……... | Name ……... |
| Date……... | Date……..…..……... |

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If you are not taking on shared care for this patient please state the reason why and return this letter to the Hospital Specialist.
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