PAN MERSEY AREA PRESCRIBING COMMITTEE
PRESCRIBING POLICY STATEMENT
FIRST APC BOARD DATE: 28 SEP 2016
LAST APC BOARD DATE: 26 SEP 2018

NHS Pan Mersey Area Prescribing Committee

DEGARELIX subcutaneous (SC) injection (Firmagon®)

AMBER

The Pan Mersey Area Prescribing Committee recommends the prescribing of DEGARELIX SC injection (Firmagon®) following specialist initiation for treating advanced hormone-dependent prostate cancer in people with spinal metastases in accordance with NICE TA404

PATIENT RETAINED BY SPECIALIST

SHARED CARE NHS WIRRAL CCG

Degarelix is recommended as an option for treating advanced hormone-dependent prostate cancer in people with spinal metastases, only if the commissioner can achieve at least the same discounted drug cost as that available to the NHS in June 2016 (NICE TA404)[1]

This guidance is not intended to affect the position of patients whose treatment with degarelix, an LHRH antagonist, was started within the NHS before this guidance was published. Treatment of those patients may continue without change to whatever funding arrangements were in place for them before this guidance was published until they and their NHS clinician consider it appropriate to stop.

There may be a relationship between the testosterone flare when hormonal treatment starts and spinal cord compression in people with spinal metastases from the prostate. The risk of spinal cord compression may be lower in people having degarelix compared with LHRH antagonists because degarelix does not produce an initial flare in testosterone levels. NICE concluded that it is not possible to reliably identify and precisely define a subgroup of patients who face a higher risk of developing spinal cord compression from the broader population of patients with spinal metastases from the prostate.

NICE concluded that the likely position of degarelix in the treatment pathway is as first-line hormonal therapy for treating advanced hormone-dependent prostate cancer; that is, at the same point in the pathway as the LHRH antagonists.

The Pan Mersey first choice LHRH analogue for prostate cancer is triptorelin intramuscular injection. Consult separate policy statement: http://www.panmerseyapc.nhs.uk/recommendations/documents/PS46.pdf

Also consult the Pan Mersey Degarelix (Firmagon) prescribing support information: http://www.panmerseyapc.nhs.uk/prescribing_support/documents/PSI2.pdf?UNLID=6553159220187

Note: Patients who are not eligible for treatment under this statement may be considered on an individual basis where their GP or consultant believes exceptional circumstances exist that warrant deviation from the rule of this policy. In this situation, follow locally defined processes.

DEGARELIX subcutaneous (SC) injection (Firmagon®)

EFFECTIVENESS[1]

Degarelix is a selective gonadotrophin-releasing hormone antagonist that reduces the release of gonadotrophins by the pituitary, which in turn reduces the secretion of testosterone by the testes. Gonadotrophin-releasing hormone is also known as luteinising hormone-releasing hormone. Because gonadotrophin-releasing hormone antagonists do not produce a rise in hormone levels at the start of treatment, there is no initial testosterone surge or tumour stimulation, and therefore no potential for symptomatic flares.

NICE concluded that degarelix was non-inferior to luteinising hormone-releasing hormone (LHRH) antagonists in suppressing testosterone levels and acknowledged that it is beneficial for avoiding testosterone flare.

SAFETY

The most common adverse reactions with degarelix are related to the effects of testosterone suppression, including hot flushes and weight increase, or injection site reactions (such as pain and erythema).Serious injection site reactions were very rarely reported such as injection site infection, injection site abscess or injection site necrosis that could require surgical treatment/drainage.[1]

Fatigue and dizziness are common adverse reactions that might influence the ability to drive and use machines.[2]

Contraindications are hypersensitivity to the active substance or to any of the excipients listed in the SPC. No formal drug-drug interaction studies have been performed.[2]

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.[2] See SPC for full details.

COST[3]

Degarelix 120mg vial (x2) £260.00 (first dose)
Degarelix 80mg vial (x1) £129.37 (monthly); £1,552.44 (12 months)
Triptorelin (Decapeptyl SR) 11.25mg (x1) £207.00 (every 3 months); £828.00 (12 months)
Triptorelin (Decapeptyl SR) 22.5mg (x1) £414.00 (every 6 months); £828.00 (12 months)
Bicalutamide 50mg tablets £11.20/28

For degarelix the commissioner must achieve at least the same discounted drug cost as that available to the NHS in June 2016.[1] NICE used a rate of spinal cord compression of 0.96% (reflective of the estimated rate of spinal cord compression in people with metastatic prostate cancer). Because of the small number of people who may have treatment, NICE considered that clinical practice will not change substantially as a result of this guidance.[1]

PATIENT FACTORS

There is no need to adjust the dose for the elderly or in patients with mild or moderate liver or kidney function impairment. Patients with severe liver or kidney impairment have not been studied and caution is therefore warranted.

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.[2]

PRESCRIBING INFORMATION: Degarelix is for subcutaneous administration (SC) only and should be administered in the abdominal region. Starting dose: 240 mg administered as two SC injections of 120 mg (3ml) each. Maintenance dose – monthly administration: 80 mg (4ml) administered as one SC injection.**The first maintenance dose should be given one month after the starting dose. Since degarelix does not induce a testosterone surge it is not necessary to add an anti-androgen (e.g. bicalutamide) as surge protection at initiation of therapy.** Clinical studies have shown that testosterone (T) suppression occurs immediately after administration of the starting dose with 96% of the patients having serum testosterone levels corresponding to medical castration (T≤0.5 ng/ml) after three days and 100% after one month.[2]

IMPLEMENTATION NOTES: The starting dose (240mg) and the first 80mg maintenance dose should be administered by the specialist (or as per local arrangements for Wirral CCG). Prescribing should be retained in secondary care until after the first follow-up appointment (or as per local arrangements for Wirral CCG). All patients receiving degarelix should be reviewed by the specialist and there should be clear documentation of efficacy and on-going need for treatment documented in communication to the patient's GP. Once treatment has been assessed as efficacious, prescribing may be transferred to primary care, but the patient should remain under specialist review. The therapeutic effect of degarelix should be monitored by clinical parameters and prostate specific antigen (PSA) serum levels and will be undertaken by specialists initiating treatment. In case the patient's clinical response appears to be sub-optimal, it should be confirmed that serum testosterone levels are remaining sufficiently suppressed.

For the 80mg maintenance dose, the pack contains one vial of powder and one pre-filled syringe with solvent. To prevent foam formation, the vial must not be shaken. A ring of small air bubbles on the surface of the liquid is acceptable. The reconstitution procedure usually takes a few minutes, but may take up to 15 minutes in some cases. The injected liquid forms a gel from which degarelix is released over a period of one month.[2]

REFERENCES

1. National Institute for Health and Care Excellence. Degarelix for treating advanced hormone-dependent prostate cancer. TA404, 24th August 2016. Accessed 07 September 2016 at https://www.nice.org.uk/guidance/ta404
2. Ferring Pharmaceuticals Ltd. Summary of Product Characteristics and Patient Information Leaflets - Firmagon 120mg SC injection and Firmagon 80mg SC injection; Accessed 12th July 2018 at: http://www.medicines.org.uk/emc/
3. NHSBSA dm+d browser. Accessed 12th July 2018. https://apps.nhsbsa.nhs.uk/DMDBrowser/DMDBrowser.do