This policy statement is approved by Halton, Knowsley, Liverpool, Southport and Formby, South Sefton, St Helens, Warrington and West Lancashire CCGs

Halton | Knowsley | Liverpool | Southport and Formby | South Sefton | St Helens | ~~Warrington~~ | West Lancashire

PAN MERSEY APC

NHS
Pan Mersey
Area Prescribing Committee

Prescribing Support Information

DEGARELIX (Firmagon®)

AMBER patient retained by specialist

Your patient has been identified as being suitable to receive degarelix in accordance with the indications detailed below. He has been started on treatment and has been reviewed to assess the efficacy and adverse effects of the treatment by the specialist team.

Degarelix has been considered as appropriate for prescribing in primary care and the information contained in this document has been provided to support you to prescribe it for your patient in the community.

Pan Mersey Area prescribing committee has RAG rated degarelix as Amber Patient Retained which means it is suitable for prescribing in primary care following specialist initiation for the treatment of advanced hormone dependant prostate cancer in people with spinal metastasis. Your patient will remain under the care of the specialist team whilst receiving this medicine.

Degarelix

Degarelix is a selective gonadotrophin-releasing hormone antagonist that reduces the release of gonadotrophins by the pituitary gland, 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.

Following a review, 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 agonists. It is, however, of particular benefit for patients with spinal metastases as the testosterone flare which may lead to spinal cord compression is avoided.

Indication

Degarelix (Firmagon ®) is licensed for the treatment of adult male patients with advanced hormone-dependent prostate cancer.

Name of Drug, Form and Dose

Degarelix is administered as a subcutaneous s/c injection in the abdominal region. It should be given in areas where the patient will not be exposed to pressure eg not around waistband or close to ribs. The injection site should vary periodically.

Available Preparations

Degarelix is available in two strengths: 120mg and 80mg vials. Only the 80mg vials will be used in primary care.

The 80mg pack contains one vial of powder and one pre-filled syringe with solvent.

80-mg vial (with diluent) - after reconstitution, each ml of solution contains 20 mg of degarelix.

Starting dose: 240mg administered as two subcutaneous injections of 120mg (3ml) **by secondary care.**

Maintenance dose: 80 mg (4ml) monthly administered as a subcutaneous injection starting one month after the starting dose and continued monthly.

Monitoring recommendations

In any patient with known or suspected hepatic disorder, the specialist team should advise the GP of the frequency of LFT monitoring required and advise GP on the appropriate course of action when they report any raised LFT.

If there are concerns about the bone mineral density (BMD), then the specialist should investigate on initiation. The specialist will then advise the GP if the patient will need a further BMD test with the timescale.

When the drug is initiated, the specialist will counsel the patient that degarelix may affect diabetes control and therefore they may need to monitor their blood glucose more frequently. The GP would continue to monitor diabetic patients as usual as part of their ongoing care.

The therapeutic effect of degarelix should be monitored by clinical parameters and prostate specific antigen (PSA) serum levels. This will be undertaken by the specialist initiating treatment.

Caution is advised in patients susceptible to QT-prolongation.

How long the medicine should be prescribed for

Indefinitely or as indicated by the specialist.

Contra-indications

Hypersensitivity to the active substance or to any of the excipients.

Adverse effects

Very common (≥1/10): Hot flush*, injection site adverse events
Common (≥1/100 to <1/10): anaemia*, weight increase*, insomnia, dizziness, headache, diarrhoea, nausea, liver transaminases increased, hyperhidrosis (inc. night sweats)*, rash, musculoskeletal pain & discomfort, gynaecomastia*, testicular atrophy*, erectile dysfunction*, chills, pyrexia, fatigue*, influenza-like illness

*known physiological consequence of testosterone suppression

Please note this list is not exhaustive – refer to SPC for the complete list.

Interaction with other medicines

For a comprehensive list consult the BNF or Summary of Product Characteristics.

Seek advice from the initiating Specialist if there are any concerns about interactions.

When to seek specialist advice

- If the patient suffers any adverse reactions
- If the patient decides to discontinue treatment for any reason
- Any deterioration in symptoms should be reported to the specialist team

General information

- Since degarelix does not induce a testosterone surge it is not necessary to add an anti-androgen (e.g. bicalutamide/cyproterone) 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.

Contact details for advice

Please refer to the contact details included in the clinic letter issued by the specialist.

Signposting

Prostate Cancer UK produce a booklet 'Living with hormone therapy' along with a factsheet which can be downloaded/ordered via their website.

https://prostatecanceruk.org/

References

1. Summary of Product Characteristics. Accessed 27.10.2020 Degarelix - Electonic Medicines Compendium
2. British National Formulary. Accessed 27.10.2020 DEGARELIX | Drug | BNF content published by NICE