Degarelix Therapy

INDICATIONS FOR USE:

INDICATION	ICD10	Regimen Code	Reimbursement Status
Treatment of adult male patients with advanced hormone-dependent prostate cancer	C61	00481a	CDS

TREATMENT:

Degarelix 240 mg is administered as two consecutive subcutaneous injections of 120 mg each on day 1. The first maintenance dose of degarelix 80mg is administered 28 days after the starting dose and continued every 28 days until disease progression or unacceptable toxicity develops.

Day	Drug	Dose	Route	Diluent & Rate	Cycle
1	Degarelix	[a]240mg	SC	n/a	1
1	Degarelix	80mg	SC		2 onwards
[a] Degarelix 240mg is administered as two consecutive sc injections of 120mg each					
Degarelix is administered as a subcutaneous injection in the abdominal region. The injection site should vary periodically. Injections should be given in areas where the patient will not be exposed to pressure e.g. not close to waistband or belt and not close to the ribs					

ELIGIBILTY:

- Indications as above

EXCLUSIONS:

- Hypersensitivity to degarelix or any of the excipients

PRESCRIPTIVE AUTHORITY:

The treatment plan must be initiated by a Consultant with expertise in the treatment of prostate carcinoma.

TESTS:

Baseline tests:

- FBC, renal and liver profile
- Bone profile
- Blood glucose

Regular tests:

- FBC, renal and liver profile as clinically indicated
- Blood glucose and bone profile as clinically indicated

Disease monitoring:

Disease monitoring should be in line with the patient's treatment plan and any other test/s as directed by the supervising Consultant.

DOSE MODIFICATIONS:

- No recommended dose modifications.

Table 1: Dose modification of degarelix in renal and hepatic impairment

Renal Impairment		Hepatic Impairment	
Mild	No dose modification necessary	Mild	No dose modification necessary
Moderate		Moderate	
Severe	No information. Caution advised	Severe	Has not been studied. Caution advised

SUPPORTIVE CARE:

EMETOGENIC POTENTIAL: Minimal (**Refer to local policy).**

PREMEDICATIONS: None

OTHER SUPPORTIVE CARE:
Calcium and vitamin D supplementation (Refer to local policy)

ADVERSE EFFECTS / REGIMEN SPECIFIC COMPLICATIONS

The adverse effects listed are not exhaustive. Please refer to the relevant Summary of Product Characteristics for full details.

- **Bone Mineral Density:** The use of LHRH agonists may cause reduction in bone mineral density. In men, preliminary data suggest that the use of a bisphosphonate in combination with an LHRH agonist may reduce bone mineral loss. Particular caution is necessary in patients with additional risk factors for osteoporosis (e.g. chronic alcohol abusers, smokers, long-term therapy with anticonvulsants or corticosteroids, family history of osteoporosis). Bone density has not been measured during treatment with degarelix.
- **Glucose Tolerance:** A reduction in glucose tolerance has been observed in males receiving LHRH agonists. This may manifest as diabetes or loss of glycaemic control in those with pre-existing diabetes mellitus. 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.
- **Hepatic Impairment:** Patients with known or suspected hepatic disorder have not been included in long-term clinical trials with degarelix. Mild, transient increases in ALT and AST have been seen, these were not accompanied by a rise in bilirubin or clinical symptoms. Monitoring of liver function in patients with known or suspected hepatic disorder is advised during treatment.
- **Cardiovascular disease:** Cardiovascular disease such as stroke and myocardial infarction has been reported in the medical literature in patients with androgen deprivation therapy. Therefore, all cardiovascular risk factors should be taken into account

DRUG INTERACTIONS:

- Since androgen deprivation treatment may prolong the QT interval, the concomitant use of degarelix with medicinal products known to prolong the QT interval or medicinal products able to induce Torsade de pointes should be carefully evaluated
- Current drug interaction databases should be consulted for more information.

ATC CODE:

Degarelix L02BX02

REFERENCES:

1. Klotz L, Boccon-Gibod L, Shore ND, et al. The efficacy and safety of degarelix: a 12-month, comparative, randomized, open-label, parallel-group phase III study in patients with prostate cancer. BJU Int 2008;102(11):1531-1538.
2. Degarelix (FIRMAGON ®) Summary of Product Characteristics. Last updated: 10/01/2020/ Accessed April 2018. Available at https://www.ema.europa.eu/en/documents/product-information/firmagon-epar-product-information_en.pdf

Version	Date	Amendment	Approved By
1	30/05/2018		Prof Maccon Keane
2	27/05/2020	Reviewed.	Prof Maccon Keane

Comments and feedback welcome at oncologydrugs@cancercontrol.ie.