Systemic Anti-Cancer Treatment Protocol

Degarelix (Firmagon)

PROTOCOL REF: MPHADEGFUR
(Version No: 1.0)

Approved for use in:

The treatment of adult males who have advanced hormone-dependent prostate cancer which has metastasised to the spine.

Dosage:

Drug	Dosage	Route	Frequency
Degarelix	240mg	Subcutaneous	First dose
Degarelix	80mg	Subcutaneous	Monthly maintenance dose

- After the initial dose, Degarelix should be switched to Triptorelin; otherwise it can be continued until disease progression or death.
- Degarelix does not induce a testosterone surge; therefore, it is not necessary to add an anti-androgen such as bicalutmide at initiation of therapy.
- Patients who have been on this therapy prior to this protocol may continue it long term under the advice of their clinician.
- It is recommended that if the patient is to remain on degarelix (and is not switched to another GnRH) then cycle 2 should be administered under specialist care before transferring to primary care.

Extravasation risk:

N/A

Contra-indications

Hypersensitivity to the active substance or any excipients.

Special warnings and precautions for use

- Long-term androgen deprivation therapy may prolong the QTc interval.
- Decreased bone density has been reported in the medical literature in men who have had orchiectomy or who have been treated with a GnRH agonist.
- 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.

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 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 and monitored.

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.

Main Toxicities:

MedDRA System Organ Class (SOC)	Very common	Common	Uncommon	Rare
Blood and lymphatic system disorders		Anaemia		Neutropenic fever
Immune system disorders			Hypersensitivity	Anaphylactic reactions
Metabolism and nutrition disorders		Weight increase	Hyperglycemia/Diabetes mellitus, cholesterol increased, weight decreased, appetite decreased, changes in blood calcium	
Psychiatric disorders		Insomnia	Depression, libido decreased*	
Nervous system disorders		Dizziness, headache	Mental impairment, hypoaesthesia	
Eye disorders			Vision blurred	
Cardiac disorders			Cardiac arrhythmia (incl. atrial fibrillation), palpitations, QT prolongation*	Myocardial infarction, cardiac failure
Vascular disorders	Hot flush*		Hypertension, vasovagal reaction (incl. hypotension)	
Respiratory, thoracic and mediastinal disorders			Dyspnoea	
Gastrointestinal disorders		Diarrhoea, nausea	Constipation, vomiting, abdominal pain, abdominal discomfort, dry mouth	
Hepatobiliary disorders		Liver transaminases increased	Bilirubin increased, alkaline phosphatase increased	
Skin and subcutaneous tissue disorders		Hyperhidrosis (incl. night sweats)* , rash	Urticaria, skin nodule, alopecia, pruritus, erythema	
Musculoskeletal,		Musculoskeletal	Osteoporosis/osteopenia,	

connective tissue and bone disorders		pain and discomfort	arthralgia, muscular weakness, muscle spasms, joint swelling/stiffness	
Renal and urinary disorders			Pollakiuria, micturition urgency, dysuria, nocturia, renal impairment, incontinence	
Reproductive system and breast disorders		Gynaecomastia*, testicular atrophy*, erectile dysfunction*	Testicular pain, breast pain, pelvic pain, genital irritation, ejaculation failure	
General disorders and administration site conditions	Injection site adverse reactions	Chills, pyrexia, fatigue*, Influenza-like illness	Malaise, peripheral oedema	

Investigations and treatment plan

	Pre	Cycle 1	Cycle 2 (if continued on with degarelix)	Ongoing
Medical Assessment	X			As clinically indicated
Nursing Assessment		X	X	Every cycle
SACT assessment			X	
U&E & LFT	X	X	X	Every cycle
Informed Consent	X			
PS recorded		X	X	Every cycle
Toxicities documented	X	X	X	Every cycle
PSA	X		X	Every cycle
Pulse	X	X	X	Every Cycle
Blood Pressure	X	X	X	Every Cycle
Testosterone Levels	X			Periodically
Blood glucose	X	X	X	Every cycle
Weight recorded	X	X		Every cycle

GP Responsibilities

A shared care agreement between the trust and the patients GP can be implemented depending on the patient's location within Merseyside, Cheshire or Wales. Please refer to the following document for information regarding this arrangement.

https://www.panmerseyapc.nhs.uk/media/2072/degarelix.pdf

References:

Electronic Medicines Compendium. Firmagon 120mg injection. Available from: https://www.medicines.org.uk/emc/product/6537/smpc [accessed on 13-9-18]

Nice guideline. Degarelix for treating advanced hormone-dependent prostate cancer. Available from: https://www.nice.org.uk/guidance/ta404/resources/degarelix-for-treating-advanced-hormonedependent-prostate-cancer-pdf-82604542759621 [accessed on 13-9-18]

Pan Mersey. *Degarelix subcutaneousinjection.* Available from: https://www.panmerseyapc.nhs.uk/media/2072/degarelix.pdf [accessed on: 28-11-2018]