

Guideline on Prescribing of Gonadorelin Analogues and Gonadotrophin Releasing Hormone Antagonists in the treatment of Prostate Cancer

1. BACKGROUND

Metastatic cancer of the prostate usually responds to hormonal treatment aimed at androgen depletion. Standard treatments include use of a gonadorelin analogue, as an alternative to surgery.

The gonadotrophin releasing hormone antagonist, degarelix, is used to treat advanced hormone-dependent cancer. It is preferred option in patients in whom tumour “flare” (associated with initial treatment with gonadorelin analogue) is anticipated to cause problems (see below).

2. INDICATION

Gonadorelin Analogues

- Locally advanced prostate cancer
- Adjuvant treatment to radiotherapy or radical prostatectomy in patients with high risk localised or locally advanced prostate cancer
- Neoadjuvant treatment prior to radiotherapy in patients with high risk localised or locally advanced prostate cancer
- Metastatic prostate cancer

Gonadotrophin Releasing Hormone Antagonists (Degarelix) **Amber drug – see shared care framework**

- Symptomatic, advanced metastatic, high PSA prostate cancer patients who are at risk of impending spinal cord compression or ureteric obstruction

3. DOSE AND DURATION OF TREATMENT WITH GONADORELIN ANALOGUES

Patients should be prescribed a licensed treatment, with the lowest acquisition cost.

Drug Name	Trade name	Monthly dose	Three monthly dose	Six monthly dose
Goserelin	Zoladex	3.6mg	10.8mg (Zoladex LA [®])	N/A
Leuprorelin	Prostap	3.75 mg (Prostap SR DCS [®])	11.25mg (Prostap 3 DCS [®])	
Triptorelin	Decapeptyl SR [®]	3mg	11.25mg	22.5mg

Injection sites should be changed each time.

4. CONTRAINDICATIONS AND CAUTIONS

Treatments are contraindicated in known severe hypersensitivity to the active substance or to any of the excipients of the product

Patients at risk of ureteric obstruction or spinal cord compression should be considered carefully and closely supervised in the first few weeks of treatment with gonadorelin analogues. These patients should be considered for treatment with degarelix or prophylactic treatment with anti-androgens

5. ADVERSE EFFECTS

Most commonly reported adverse effects with treatments include: injection site reactions, decreased libido, erectile dysfunction, testicular atrophy, gynaecomastia, hot flushes, hyperhidrosis, rash, mood changes, depression, insomnia, paraesthesia, musculoskeletal pain and discomfort, anaemia, weight changes, nausea, diarrhoea, changes in blood pressure, heart failure, myocardial infarction, reduction in bone mass. Changes in blood lipids and alteration of glucose tolerance have also been reported which may affect diabetic control. Elevated liver enzymes and hepatic dysfunction have also been reported.

In cases where a "tumour flare" occurs after gonadorelin analogues, an exacerbation may occur in any symptoms or signs due to disease, for example, bone pain, urinary obstruction, weakness of the lower extremities and paraesthesia. These symptoms subside on continuation of therapy.

6. INTERACTIONS

No recognised drug interactions reported

Details of contraindications, cautions, drug interactions and adverse effects listed for all drugs above are not exhaustive. For further information always check with BNF www.bnf.org.uk or SPC (www.medicines.org.uk).

7. MONITORING

Baseline: U&Es, FBC and PSA levels.

During treatment: PSA levels should be monitored by the specialist on a six monthly basis, increased to 3 monthly if rise in PSA levels > 20%.

(Phlebotomy may be requested by specialist – results will be reviewed by specialist.)

If the GP suspects the patient is experiencing ureteric obstruction or spinal cord compression the hospital specialist should be contacted.

The GP should refer promptly to hospital specialist when any loss of clinical efficacy occurs, if disease progression suspected.

8. INFORMATION TO THE PATIENT

Patients should be informed of risks and benefits of treatment, including frequency of administration, side effects of treatment, symptoms which should be reported to clinician.

9. RESPONSIBILITIES

Stage of Treatment	Hospital Team Responsibilities	GP Responsibilities
Initiation	Assess suitability for treatment and recommend that treatment is initiated Provide information to patient on treatment required	Initiate treatment following advice of specialist team
Maintenance	Monitor response to treatment and advise GP of necessary changes to therapy. Evaluation of ADRs reported by the GP.	Monitor patient for adverse effects and report to specialist team where necessary. Liaise with the hospital team in the event of intolerance to therapy, disease progression or loss of efficacy.

Contact details:

During Office hours: Specialist as per clinic letter

Out of hours: On-call registrar for Urology (via switchboard – 01482 875875).

APPROVAL PROCESS

Written by:	Marie Miller, Interface Pharmacist
Consultation process:	Urology team HEY
Approved by:	<i>MMIG (May 2014)</i>
Ratified by:	<i>HERPC: July 2014 Reviewed January 2018</i>
Review date:	January 2021