

Information Sheet Bicalutamide for Prostate Cancer

Treatment of prostate cancer depends primarily on the stage of disease, histology, but also on the patient's age, general health and personal preference. Treatment strategies are tailored towards localised, locally advanced or advanced (node positive or metastatic disease) as follows:

	Treatment options
Localised prostate cancer:	<ul style="list-style-type: none"> • Watchful waiting • Radiotherapy • Neoadjuvant goserelin + radiotherapy • Radical prostatectomy • Active surveillance
Locally advanced prostate cancer:	<ul style="list-style-type: none"> • Radiotherapy • Radical prostatectomy • Radiotherapy or prostatectomy + adjuvant anti-androgen
Advanced prostate cancer: (node positive or metastatic)	<ul style="list-style-type: none"> • Surgical castration by bilateral orchidectomy • Radiotherapy • Medical castration: <ul style="list-style-type: none"> ➢ LHRH analogues ➢ Anti-androgens

LHRH analogues = buserelin, goserelin, leuprorelin, triptorelin.

Anti-androgens = cyproterone acetate, flutamide, bicalutamide.

Bicalutamide is a non-steroidal anti-androgen which acts by blocking binding of dihydrotestosterone and testosterone to its receptor thereby preventing androgen action. It is available in two strengths, 50mg and 150mg and each are only used in specific circumstances as follows:

	Bicalutamide 50mg od	Bicalutamide 150mg od
Localised prostate cancer: (small tumour with no tumour spread)	x	x CSM advise (Oct 2003): Bicalutamide 150mg is no longer indicated for localised prostate cancer, as there is a trend towards an increased death rate compared to a watchful waiting approach. Patients should be reviewed at the earliest opportunity and treatment discontinued.
Locally advanced prostate cancer: (larger tumours of tumours with spread to lymph nodes but not to other organs)	x	✓ 2 nd line if LHRH analogues are not tolerated. Used either as: <ul style="list-style-type: none"> • Monotherapy (until disease progression) • Adjuvant: for 3 years following radiotherapy • Neoadjuvant: 3 months prior to radiotherapy and continuing until 2 months post radiotherapy (NOT LICENSED)
Advanced prostate cancer: (node positive or metastatic)	✓ 2 nd or 3 rd line. Used in combination with LHRH analogue OR surgical castration until disease progression.	x

x = not indicated ✓ = indicated

Summary of Adverse effects

(see summary of product characteristics for full list)

Bicalutamide is generally well tolerated and has rarely required discontinuation due to adverse effects. Common (>1%) side effects include:

Gynaecomastia, breast tenderness, hot flushes, pruritis, nausea, asthenia, dry skin, decreased libido, impotence, alopecia, weight gain.

Clinically relevant drug interactions:

Effect of warfarin may be enhanced. Caution with ciclosporin, calcium channel blockers, cimetidine and ketoconazole.

Responsibilities:

Acute Trust:

1. Initiate bicalutamide treatment and stabilise treatment.
2. Seek shared prescribing agreement with GP, clearly indicating if bicalutamide is used outside licensed indications (i.e. when used as neoadjuvant treatment)
3. Outpatient appointments at least every 6 months (based on clinical need)
4. Blood tests: LFTs every 6 months, PSA when appropriate
5. Communicate blood test results to GP and indicate whether treatment should be continued after each follow up appointment

GP:

1. To continue bicalutamide treatment once patient has been stabilised on treatment.
2. Monitor patients overall health status
3. Monitor for side effects and refer back to consultant if troublesome
4. Be aware of drug interactions when initiating new therapy (seek advice as required)
5. Ensure patient attends 6-monthly outpatient appointments
6. Refer back to consultant if there is any evidence of disease progression such as bone pain or increased urinary symptoms

References:

- National Institute for Clinical Excellence. Guideline on Cancer services. Improving outcomes in urological cancers- The Manual. September 2002
- London Cancer New Drugs Group. APC/DTC briefing. The role of neoadjuvant androgen deprivation therapy (ADT) in the treatment of prostate cancer. March 2005.
- London New Drugs Group. APC/DTC briefing. Review of the role of bicalutamide 150mg monotherapy in early and locally advanced prostate cancer. June 2003.
- MTRAC: Bicalutamide for the treatment of prostate cancer. November 2003
- Committee on safety of Medicines. Casodex 150mg (bicalutamide): no longer indicated for treatment of localised prostate cancer. Letter to Health Professionals 28 October 2004. CEM/CMO/2003/15 (<http://medicines.mhra.gov.uk/about/agency/regframework/csm/csmhome.htm> Accessed December 2006).
- Electronic Medicines Compendium. Casodex tablets 50mg. Last updated 27 January 2004
- Electronic Medicines Compendium. Casodex 150mg film coated. Last updated 6 February 2007

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