BicalutamideTherapy

INDICATIONS FOR USE:

INDICATION	ICD10	Regimen Code	Reimbursement Status
Treatment of advanced prostate cancer in combination with luteinizing-hormone releasing hormone (LHRH) analogue therapy or surgical castration	C61	00482a	CDS

TREATMENT:

Bicalutamide 50 mg is administered daily on a continuous basis until disease progression or unacceptable toxicity develops.

Day	Drug	Dose	Route	Diluent & Rate	Cycle
1	Bicalutamide	50mg	PO	n/a	Continuous

ELIGIBILTY:

- Indications as above

EXCLUSIONS:

- Hypersensitivity to bicalutamide or any of the excipients
- Co-administration of terfenadine, astemizole or cisapride with bicalutamide is contra-indicated

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
- Blood glucose

Regular tests:

- FBC, renal and liver profile as clinically indicated
- Blood glucose 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 bicalutamide in renal and hepatic impairment

Renal Impairment	Hepatic Impairment
No dose modification necessary. No information in patients with CrCl < 30ml/min.	No dose modification necessary in mild impairment. Increased accumulation may occur in patients with moderate to severe hepatic impairment.

SUPPORTIVE CARE:

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

PREMEDICATIONS: None

OTHER SUPPORTIVE CARE: No specific recommendations

ADVERSE EFFECTS / REGIMEN SPECIFIC COMPLICATIONS:

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

- **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. Consideration should therefore be given to monitoring blood glucose in patients receiving bicalutamide in combination with LHRH agonists.
- **Hepatic Impairment:** Bicalutamide is extensively metabolised in the liver. Data suggests that its elimination may be slower in subjects with severe hepatic impairment and this could lead to increased accumulation of bicalutamide. Therefore, bicalutamide should be used with caution in patients with moderate to severe hepatic impairment. Periodic liver function testing should be considered due to the possibility of hepatic changes. The majority of changes are expected to occur within the first 6 months of bicalutamide therapy.
- **Contraception:** Antiandrogen therapy may cause morphological changes in spermatozoa. Patients who receive bicalutamide tablets, and their partners should follow adequate contraception during and for 130 days after bicalutamide therapy.

DRUG INTERACTIONS:

- Since androgen deprivation treatment may prolong the QT interval, the concomitant use of bicalutamide with medicinal products known to prolong the QT interval or medicinal products able to induce Torsade de pointes should be carefully evaluated.
- Bicalutamide has been shown to inhibit cytochrome P450 (CYP3A4), as such caution should be exercised when coadministered with drugs metabolised predominantly by CYP 3A4.
- Current drug interaction databases should be consulted for more information.

ATC CODE:

Bicalutamide L02BB03

REFERENCES:

1. Schellhammer PF, Sharifi R, Block NL, et al. Clinical benefits of bicalutamide compared with flutamide in combined androgen blockade for patients with advanced prostatic carcinoma: final report of a double-blind, randomized, multicenter trial. Casodex Combination Study Group.Urology 1997;50(3):330-336.
2. Bicalutamide Summary of Product Characteristics. Last updated: 21/06/2019. Accessed May2020. Available at https://www.hpra.ie/img/uploaded/swedocuments/Licence_PA1019-008-001_21062019175249.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.