

To be sold by retail on the prescription of oncologist only

Casodex[®] (Bicalutamide 50mg)

Abbreviated Prescribing Information

COMPOSITION:

Each film-coated tablet contains: Bicalutamide IP 50 mg

THERAPEUTIC INDICATIONS

Treatment of advanced prostate cancer in combination with LHRH analogue therapy or surgical castration.

POSODOLOGY AND METHOD OF ADMINISTRATION

Adult males including the elderly: one tablet (50 mg) once a day.

Treatment with Casodex should be started at least 3 days before commencing treatment with an LHRH analogue, or at the same time as surgical castration.

CONTRAINDICATIONS

Hypersensitivity to the active substance or to any of the excipients.

Pregnancy and lactation

Co-administration of terfenadine, astemizole or cisapride with Casodex is contraindicated (Please refer to full prescribing information).

WARNINGS & PRECAUTIONS

Casodex[®] should be used with caution in patients with moderate to severe hepatic impairment. Consideration should be given to monitoring blood glucose in patients receiving Casodex in combination with LHRH agonists. Casodex has been shown to inhibit cytochrome P450 (CYP 3A4), as such caution should be exercised when co-administered with drugs metabolised predominantly by CYP 3A4. Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine. In patients with a history of or risk factors for QT prolongation and in patients receiving concomitant medicinal products that might prolong the QT interval, physicians should assess the benefit risk ratio including the potential for Torsade de pointes prior to initiating Casodex.

PREGNANCY AND LACTATION

Casodex is contra-indicated in females and must not be given to pregnant women or nursing mothers.

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UNDESIRABLE EFFECTS

The most frequently reported adverse reactions were anemia, dizziness, hot flush, esthenia, edema and hematuria. Please refer to full prescribing information or detailed assessment of adverse events.

INTERACTIONS

In vitro studies have shown that R-bicalutamide is an inhibitor of CYP 3A4, with lesser inhibitory effects on CYP 2C9, 2C19 and 2D6 activity. For drugs with a narrow therapeutic index such an increase could be of relevance. Concomitant use of terfenadine, astemizole and cisapride is contraindicated. If 'Casodex' is started in patients who are already receiving coumarin anticoagulants, prothrombin time should be closely monitored. The concomitant use of Casodex with medicinal products known to prolong the QT interval or medicinal products able to induce Torsade de pointes such as class IA or class III antiarrhythmic medicinal products, methadone, moxifloxacin, antipsychotics, etc. should be carefully evaluated

PHARMACOLOGICAL PROPERTIES

Mechanism of action

Casodex is a non-steroidal antiandrogen, devoid of other endocrine activity. It binds to androgen receptors without activating gene expression, and thus inhibits the androgen stimulus. Regression of prostatic tumours results from this inhibition.

Pharmacokinetic properties

Casodex is well absorbed following oral administration. Casodex is highly protein bound (racemate 96% (R)-enantiomer >99%) and extensively metabolised (via oxidation and glucuronidation): Its metabolites are eliminated via the kidneys and bile in approximately equal proportions. The (S)-enantiomer is rapidly cleared relative to the (R)-enantiomer, the latter having a plasma elimination half-life of about 1 week. On daily administration of Casodex, the (R)-enantiomer accumulates about 10 fold in plasma as a consequence of its long half-life.

PHARMACEUTICAL PARTICULARS

Excipients

Lactose Monohydrate
Magnesium Stearate
Hyromellose
Macrogol 300
Povidone
Sodium Starch Glycolate
Titanium Dioxide

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Shelf life

5 years

Storage

Do not store above 30°C and protect from moisture

Presentation

White film-coated tablet 50 mg IP bicalutamide

Casodex® is a registered trademark of AstraZeneca group of companies.

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For more information, refer full prescribing information Version 2 dated 20th April 2017