Casodex

(bicalutamide) - AstraZeneca

THERAPEUTIC CLASS

Nonsteroidal antiandrogen

INDICATIONS

Treatment of stage D_2 metastatic carcinoma of the prostate in combination with a luteinizing hormone-releasing hormone (LHRH) analog.

ADULT DOSAGE

Adults: Usual: 50mg qd (am or pm) in combination with an LHRH analog. Take at the same time each day and start at the same time as treatment with an LHRH analog.

HOW SUPPLIED

Tab: 50mg

CONTRAINDICATIONS

Women, pregnancy.

WARNINGS/PRECAUTIONS

Cases of death or hospitalization due to severe liver injury (hepatic failure) reported. Hepatitis and marked increases in liver enzymes leading to drug d/c reported; measure serum transaminase levels prior to treatment, at regular intervals for the 1st 4 months, and periodically thereafter. Measure serum ALT immediately if signs/symptoms of liver dysfunction occur; d/c immediately with close follow-up of liver function if jaundice occurs or ALT rises >2X ULN. Reduction in glucose tolerance reported; monitor blood glucose. Regularly assess serum prostate-specific antigen (PSA) to monitor response; evaluate for clinical progression if PSA levels rise during therapy. For patients with objective disease progression with an elevated PSA, consider a treatment period free of antiandrogen, while continuing the LHRH analog. Caution with moderate-severe hepatic impairment; monitor LFTs periodically on long term therapy.

ADVERSE REACTIONS

Pain, hot flashes, HTN, constipation, nausea, diarrhea, anemia, peripheral edema, dizziness, dyspnea, rash, nocturia, hematuria, urinary tract infection, gynecomastia.

DRUG INTERACTIONS

Can displace coumarin anticoagulants from binding sites; monitor PT and consider anticoagulant dose adjustment. Caution with CYP3A4 substrates. May increase levels of midazolam.

PREGNANCY

Category X, not for use in nursing.

MECHANISM OF ACTION

Nonsteroidal antiandrogen; inhibits the action of androgens by binding to cytosol androgen receptors in target tissue.

PHARMACOKINETICS

Absorption: Well-absorbed; C_{max}=0.768µg/mL; T_{max}=31.3 hrs. **Distribution:** Plasma protein binding (96%). **Metabolism:** Liver via oxidation and glucuronidation. **Elimination:** Urine, feces; $T_{1/2}$=5.8 days.

ASSESSMENT

Assess for drug hypersensitivity, diabetes, hepatic impairment, and possible drug interactions. Measure serum transaminase levels.

MONITORING

Measure serum transaminase levels at regular intervals for the first 4 months of treatment, then periodically thereafter. Measure serum ALT for signs/symptoms of liver dysfunction. Monitor LFT in hepatic impaired patients on long term therapy. Regularly monitor serum PSA levels. Monitor for hypersensitivity reactions and blood glucose levels.

PATIENT COUNSELING

Advise not to interrupt or stop taking the medication without consulting their physician. Inform that somnolence may occur; advise to use caution when driving or operating machinery. Advise to monitor blood glucose levels while on therapy.

ADMINISTRATION/STORAGE

Administration: Oral route. **Storage:** 20-25°C (68-77°F).