AstraZeneca

Title

Specified clinical experience investigation on the single use of Casodex® Tablet 80 mg

Summary

A post-marketing survey was conducted between April 2009 and March 2011 to evaluate safety and clinical efficacy of monotherapy with Casodex® (bicalutamide) Tablets 80 mg once-daily in patients with prostate cancer who had not received any hormonal therapy. Of 704 patients enrolled in the survey from 187 medical institutions in Japan, 697 were evaluated for safety, and 411 continued the monotherapy for 12 months until completion of the survey. Adverse drug reactions were observed in 316 patients (incidence: 45.3%), but no new issue was found regarding the safety of Casodex®. Breast pain and breast enlargement were observed in 221 (31.7%) and 147 cases (21.1%), respectively, and in most cases the symptoms were mild and no specific treatment was required. The average of PSA values remarkably decreased after starting the therapy, and remained within the normal range until the end of the survey after 12 months treatment. Sexual satisfaction and erectile ability were maintained well, and average serum testosterone slightly increased and remained at increased levels during the observation period. The above results showed that the monotherapy with Casodex®

80 mg once-daily is highly tolerable and an effective therapeutic option for prostate cancer.

(192 words / 200 words)