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All General Practitioners
Community Pharmacists
Medical Directors of HSS Trusts, for cascade to:
- Consultant Oncologists
- Consultant Urologists
Directors of Public Health in HSS Boards
Directors of Nursing in Boards & Trusts
Directors of Pharmacy in Boards & Trusts
GP Advisers in HSS Boards
Prescribing Advisers in HSS Boards
Regional Medicines & Poisons Information Centre

29 October 2003

Dear Colleague

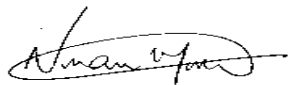
RE: CASODEX 150mg (BICALUTAMIDE): NO LONGER INDICATED FOR TREATMENT OF LOCALISED PROSTATE CANCER

Attached is advice on Casodex 150mg (bicalutamide) from Professor Gordon Duff, Chairman of the Committee on Safety of Medicines. Following review of new clinical trial data, Casodex 150mg is no longer licensed for the treatment of localised prostate cancer. "Localised" is considered to be a relatively small tumour with no tumour spread outside the prostate gland. Patients receiving Casodex 150mg for localised prostate cancer should be reviewed at the earliest opportunity and Casodex treatment discontinued.

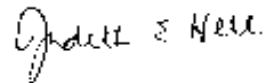
Yours sincerely



HENRIETTA CAMPBELL (DR)
Chief Medical Officer



NORMAN MORROW (DR)
Chief Pharmaceutical Officer



JUDITH HILL (MISS)
Chief Nursing Officer

This letter is available at www.dhsspsni.gov.uk and also on the DHSSPS Extranet which can be accessed directly at <http://extranet.dhsspsni.gov.uk> or by going through the HPSS Web at <http://www.n-i.nhs.uk> and clicking on DHSSPS.

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Dear Health Professional

CASODEX 150 MG (BICALUTAMIDE): NO LONGER INDICATED FOR TREATMENT OF LOCALISED PROSTATE CANCER

I am writing to inform you that following review of new clinical trial data, Casodex 150mg (bicalutamide) is no longer licensed for the treatment of localised prostate cancer. "Localised" is considered to be a relatively small tumour, with no tumour spread outside the prostate gland.

New Data

Recent results from a study of Casodex (bicalutamide) in early prostate cancer have shown that in patients with localised prostate cancer who would otherwise have been managed only by watchful waiting, there is a trend for an increase in the number of deaths in patients receiving Casodex 150mg when compared with patients who received placebo [196 (25.2%) deaths versus 174 (20.5%) deaths, hazard ratio (HR) =1.23, 95% confidence interval 1.00 - 1.50]. This analysis is at median follow-up of over 5 years. (Watchful waiting is where the patient is monitored and treatment is only started when there are signs that the disease is getting worse.)

Committee on Safety of Medicines (CSM) advice

CSM has advised that the balance of risk to benefit in patients with localised prostate cancer is unfavourable. Consequently, Casodex 150mg should not be used for the treatment of these patients.

Casodex 150mg is also used in patients with locally advanced prostate cancer, as immediate therapy either alone or as adjuvant to treatment by radical prostatectomy or radiotherapy (locally advanced is considered to be a larger tumour or tumours with spread to lymph nodes, but not involving spread to other organs). CSM advised that the overall risk benefit remained positive in this group, however they concluded that for some patients at lower risk of disease progression in this group who are also receiving surgery or radiotherapy, Casodex therapy might not be suitable as an initial therapy. Specific advice is reflected at section 5.1 Pharmacodynamics of the updated Summary of Product Characteristics.

Other approved uses of Casodex

The risk: benefit for other uses is not affected by these new data. These are:

- * Casodex 150mg in the management of patients with locally advanced, non-metastatic prostate cancer for whom surgical castration or other medical intervention is not considered appropriate or acceptable.

* Casodex 50mg in advanced prostate cancer in combination with medical castration.

Advice to prescribers

Patients receiving Casodex 150mg for localised prostate cancer should be reviewed at the earliest opportunity, and Casodex treatment discontinued.

Any patient receiving Casodex for other uses and who is concerned should discuss this with his doctor.

A "Dear Healthcare Professional" letter will be sent out by the manufacturer to general practitioners, oncologists and urologists on the 28 October 2003. An updated Summary of Product Characteristics will be attached. Similar action has been taken in several other European countries and in Canada.

Professor Gordon Duff
Chairman, Committee on Safety of Medicines