PUBLIC ADVISORY
Important Safety Information Regarding Casodex® 150 mg

Accelerated Deaths in Localized Prostate Cancer Patients

Health Canada has withdrawn its approval for CASODEX 150 mg for early (localized) prostate cancer.

AstraZeneca

August 19, 2003

In consultation with Health Canada, AstraZeneca Canada Inc. is advising health professionals and the public of important new safety information related to the drug CASODEX 150 mg (3 x 50 mg pills) for the treatment of early (localized) prostate cancer.

The results of a large on-going early prostate cancer study with CASODEX 150 mg have shown that in a subgroup of 1627 patients with early prostate cancer there is **an increase in the number of deaths (196 versus 174) in the CASODEX 150 mg treated patients** compared to those receiving no active treatment (placebo).

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Based on this data, it is recommended CASODEX 150 mg NOT be administered to patients in the early phase of prostate cancer. Patients currently undergoing CASODEX 150 mg therapy for early prostate cancer should consult their physician immediately and discontinuation of CASODEX should be discussed. It should be noted that **metastatic prostate cancer patients, taking CASODEX 50 mg per day are not affected by this new information.**

In November 2002, Health Canada issued a conditional approval for CASODEX 150 mg under a policy called the “Notice of Compliance with Conditions”. This approval reflects the promising nature of the first results of the on-going studies in patients with this serious disease, but are yet to be confirmed. Approval was based on study results which showed that in patients who would otherwise undergo “watchful waiting” (whereby the patient is monitored and treatment is only started when there are signs that the disease is getting worse), the immediate use of CASODEX 150 mg delayed the spread of prostate cancer when compared with “watchful waiting” alone. CASODEX 150 mg was approved in Canada for some localized prostate cancer patients unsuitable for surgery or radiotherapy that are at high risk of the disease spreading.

Further analysis, however, has shown that there is **evidence of accelerated deaths in patients with localized prostate cancer undergoing watchful waiting and CASODEX 150 mg therapy.** These deaths are unrelated to prostate cancer, however association with CASODEX 150 mg therapy cannot be ruled out.

In addition to advising patients, physicians and pharmacists of this safety information, AstraZeneca is working with Health Canada to ensure this information is reflected in the product labelling.

For further information, members of the public may contact AstraZeneca's Customer Relations office at 1 (800) 668-6000.

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Any suspected adverse reactions can also be reported to:

Canadian Adverse Drug Reaction Monitoring Program (CADRMP)
Marketed Health Products Directorate
HEALTH CANADA
Address Locator: 0201C2
OTTAWA, Ontario, K1A 1B9
Tel: (613) 957-0337 or Fax: (613) 957-0335
Toll free for consumers and health professionals:
Tel: 866 234-2345, Fax: 866 678-6789
cadrmp@hc-sc.gc.ca

The AR Reporting Form and the AR Guidelines can be found on the TPD web site or in *The Canadian Compendium of Pharmaceuticals and Specialties*.