

The Health Products and Food Branch (HPFB) posts on the Health Canada web site safety alerts, public health advisories, press releases and other notices as a service to health professionals, consumers, and other interested parties. These advisories may be prepared with Directorates in the HPFB, which includes pre-market and post-market areas as well as market authorization holders and other stakeholders. Although the HPFB grants market authorizations or licenses for therapeutic products, we do not endorse either the product or the company. Any questions regarding product information should be discussed with your health professional.

This is duplicated text of a letter from **AstraZeneca Canada Inc.** Contact the company for a copy of any references, attachments or enclosures.

PUBLIC ADVISORY
Health Canada Endorsed Important Information on
IRESSA[®] (gefitinib) 250 mg tablets

August 26, 2005

Health Canada Endorsed Important Information on IRESSA[®] (gefitinib) 250 mg tablets

Health Canada, in consultation with AstraZeneca Canada Inc., is recommending new restrictions on the use of the lung cancer drug IRESSA, the brand name for gefitinib. While IRESSA has not been shown to have a significant impact in extending patient survival, a recent study has found it to be effective in shrinking tumours in patients with a certain tumour characteristic.

IRESSA is generally used when a specific form of lung cancer fails to respond to two other types of treatments. The drug targets a protein called Epidermal Growth Factor Receptor (EGFR). Patients can be grouped into three categories based on the level of EGFR expressed in their tumour: positive, negative and unknown. The recent study suggests that patients whose tumours are EGFR expression status positive or unknown have significantly better rates of tumour shrinkage when treated with IRESSA versus a sugar pill. However, EGFR negative patients appear unlikely to benefit from IRESSA treatment.

The data from this pivotal post-marketing study will be reviewed by Health Canada in an expedited manner and the labeling will be updated.

Any suspected adverse drug reaction can be reported to:

AstraZeneca Canada Inc.
1004 Middlegate Road
Mississauga, ON L4Y 1M4
Tel : 1-800 433-0733
Fax : 1-800-267-5743

www.astrazeneca.ca

Any suspected adverse drug reactions can also be reported to:

Canadian Adverse Drug Reaction Monitoring Program (CADRMP)
Marketed Health Products Directorate
HEALTH CANADA

Address Locator: 0701C

OTTAWA, Ontario, K1A 0K9

Tel: (613) 957-0337 or Fax: (613) 957-0335

To report an Adverse Reaction (AR), consumers and Health professional may call toll free:

Tel: (613) 234-2345

Fax: (866) 678-6789

cadrmpp@hc-sc.gc.ca

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

Should you have any questions or require additional information regarding IRESSA[®], please contact your health care provider (physician, nurse or pharmacist) or AstraZeneca Medical Information at 1-800-668-6000 (English) and/or 1-800-461-3787 (French).

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