PUBLIC COMMUNICATION
Health Canada Endorsed Important Safety Information on
Femara*(letrozole)

NOVARTIS

November 24, 2005

Subject: Femara* (letrozole) should not be used in women who may become pregnant

Femara* (letrozole) is a medication authorized for use in Canada to treat breast cancer in women who are postmenopausal. Novartis Pharmaceuticals Canada Inc. ("Novartis") as the manufacturer and distributor of Femara* (letrozole), is aware that Femara* is being used to stimulate ovulation in women who are infertile, or unable to become pregnant, as a treatment to increase their chances of becoming pregnant. Novartis believes it is our responsibility to remind physicians treating infertility and their patients that:

- Femara* is authorized for use in post-menopausal women with breast cancer only.
- The use of Femara* for the purpose of inducing ovulation and increasing the chance of pregnancy is **not** an authorized use of this drug.
- Femara* is contraindicated and should not be used in women who may become pregnant, during pregnancy and/or while breastfeeding, because there is a potential risk of harm to the mother and the fetus, including risk of fetal malformations.
- If there is exposure to Femara* during pregnancy, the patient should contact her physician immediately to discuss the potential of harm to the fetus and potential risk for loss of the pregnancy.

Novartis has also issued a letter to Canadian obstetricians, gynecologists and fertility specialists advising them of this safety information. This letter can be found on the Health Canada website at: http://www.hc-sc.gc.ca/dhp-mps/medeff/advisories-avis/index_e.html

Novartis is committed to the delivery of quality pharmaceutical products and to ensuring the timely communication of safety information that is important to patients and health care professionals.

If you have questions about your current prescription, please contact your physician or pharmacist.

Managing marketed health product-related adverse reactions depends on health care professionals and consumers reporting them. Reporting rates determined on the basis of spontaneously reported post-marketing adverse reactions are generally presumed to underestimate the risks associated with health product treatments. Any case of serious or unexpected adverse reactions in patients receiving Femara* should be reported to Novartis or Health Canada at the following addresses:

Novartis Pharmaceuticals Canada Inc.
385 Bouchard Blvd.
Dorval, (Quebec) H9S 1A9
Phone:1-800-363-8883

Any suspected adverse reaction 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 professionals may call toll free:
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 Health Canada web site or in *The Canadian Compendium of Pharmaceuticals and Specialties.*

http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/form/ar-ei_form_e.html
http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/guide/ar-ei_guide-ldir_e.html

For other inquiries related to this communication, please contact Health Canada at:
Marketed Health Products Directorate
mhpd_dpsc@hc-sc.gc.ca
Tel: (613) 954-6522
Fax: (613) 952-7738

The full product monograph prepared for health care professionals and patient information can be found at: http://www.novartis.ca

For media inquiries please contact Jason Jacobs at (514) 633-7872.

[Pr] Femara* is a registered trademark