



Health Santé  
Canada Canada

Health Products and Food Branch  
Direction générale des produits de santé et des aliments

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 **Pfizer Canada Inc.**  
Contact the company for a copy of any references, attachments or enclosures.

**PUBLIC ADVISORY**  
**Health Canada Endorsed Important Safety Information on**  
**DEPO-PROVERA (medroxyprogesterone acetate)**



June 30, 2005

**Subject: New Safety Information on the Use of DEPO-PROVERA  
(medroxyprogesterone acetate suspension for injection, 150 mg IM)  
associated with Bone Mineral Density Changes**

**KIRKLAND, QUEBEC – June 30, 2005** – Pfizer Canada Inc. in consultation with Health Canada, would like to inform you of important updated safety information for DEPO-PROVERA (medroxyprogesterone acetate injectable suspension, USP), indicated for conception control (prevention of pregnancy), treatment of endometriosis (tissue of the uterus abnormally growing outside of the uterus), treatment of recurrent and/or metastatic endometrial cancer (cancer of the lining of the uterus) or renal cell cancer (kidney cancer) and treatment of recurrent inoperable or metastatic breast cancer in post-menopausal women.

As a result of new clinical studies, one with premenopausal adult women (age 25-35 years) and one with adolescent women (age 12-18 years) using DEPO-PROVERA for conception control, data regarding the use of DEPO-PROVERA and its associated effect on bone mineral density are now available. The data indicate that women who use DEPO-PROVERA may lose significant bone mineral density. The longer DEPO-PROVERA is used, the more bone mineral density may be lost. Bone mineral density may not return completely once use of DEPO-PROVERA has been discontinued. This is of particular concern when DEPO-PROVERA is used in adolescence (teenager years) when bone mineral density should instead be increasing. Loss of bone mineral density can cause osteoporosis (decrease in bone mass and density) and increase the risk that bones might break, especially after menopause (the end of menstrual periods).

There have been cases of osteoporosis and fracture (broken bones) associated with the use of DEPO-PROVERA.

Patients should be aware that DEPO-PROVERA should be used as a birth control method or endometrial treatment only if other treatments have been considered to be unsuitable or unacceptable and should be used for the shortest period of time possible. The risks and benefits of treatment should be carefully re-evaluated on a regular basis in all users of this drug.

DEPO-PROVERA should not be used before menarche (the onset of menstrual periods).

Patients should inform their doctor if they use any other medications (including steroids or anti-seizure medications), have a history of bone disease or anorexia nervosa (an eating disorder), have a strong family history of osteoporosis, drink alcohol or smoke. These conditions represent additional risk factors for low bone mineral density.

Patients should talk to their doctor about how to reduce the risk of low bone mineral density, and about calcium and vitamin D intake. Patients should be aware that monitoring of bone mineral density with a bone test may be recommended for some users of DEPO-PROVERA.

This public advisory is in addition to a letter issued to health care professionals reminding them of the above-mentioned safety information. As well, the product monograph for DEPO-PROVERA has been revised to inform doctors and other healthcare professionals regarding additional guidance on the appropriate use of DEPO-PROVERA.

For more information about the revisions to the prescribing information, patients should consult their healthcare professional. Patients should NOT discontinue their medication without consulting their doctor first.

For media inquiries, please contact Sophie McCann, Pfizer Canada Inc, (514) 693-4161.

The safety of patients is a priority for Pfizer Canada Inc. Information about adverse drug reactions is gathered by both Pfizer Canada Inc. and Health Canada, via its Canadian Adverse Drug Reaction Monitoring Program (CADRMP). Any suspected adverse drug reactions in patients receiving Depo-Provera can be reported to:

**Pfizer Canada Inc.**

Safety and Medical Information  
P.O. Box 800  
Pointe-Claire, Quebec  
H9R-4V2  
1-800-463-6001

**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, consumers and health professionals may call toll free:  
Tel: 866 234-2345  
Fax: 866 678-6789  
[cadrmpp@hc-sc.gc.ca](mailto:cadrmpp@hc-sc.gc.ca)

For other inquiries, please refer to contact information:

**Bureau of Metabolism, Oncology and Reproductive Sciences (BMORS)**

E-mail: [bmors\\_enquiries@hc-sc.gc.ca](mailto:bmors_enquiries@hc-sc.gc.ca)  
Telephone: (613) 941-3171  
Fax: (613) 941-1365

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/hpfb-dgpsa/tpd-dpt/adverse\\_e.html](http://www.hc-sc.gc.ca/hpfb-dgpsa/tpd-dpt/adverse_e.html)  
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