

PUBLIC ADVISORY
Health Canada Endorsed Important Safety Information on
APO-MEFLOQUINE (Mefloquine) Tablets



Subject: Important safety information for patients taking Apo-Mefloquine (mefloquine) for the prevention of malaria

Toronto, Ontario (January, 2005) — Following discussions with Health Canada, Apotex Inc. would like to inform patients of updated safety information in the Patient Information Leaflet for Apo-Mefloquine (mefloquine), a medication used to prevent infection with malaria.

Apotex Inc. has recently updated the Patient Information Leaflet to help patients recognize symptoms and signs that may indicate rare, but potentially serious, side effects of mefloquine, including mental and heart problems. A wallet card is included in the Patient Information Leaflet, and contains the most important information. The wallet card may be cut out and carried for easy reference during travel to areas with malaria.

If you use Apo-Mefloquine to prevent malaria and you experience any of the following symptoms or signs:

- sudden onset of unexplained anxiety;
- depression;
- restlessness or irritability;
- confusion;
- or a persistently abnormal heart beat or palpitations,

you are advised to contact a doctor or health care provider. It may be necessary to stop taking Apo-Mefloquine and use another malaria prevention medicine instead. If you are unable to get another medication, you should leave the malaria area. However, be aware that you still need to take a malaria prevention medication, because leaving the malaria area may not protect you from infection with malaria.

The most frequently reported side effects with mefloquine, such as nausea, difficulty sleeping, and bad dreams are usually mild and do not cause people to stop taking the medicine. Mefloquine can rarely cause some patients to experience serious mental problems, including severe anxiety, feelings that people are against them, hallucinations (seeing or hearing things that are not there), depression, unusual behavior, or feeling confused. While there have been reports of suicidal thoughts and rare reports of suicide in patients taking mefloquine, the link between the use of mefloquine and these events has not been clearly established.

You should not take Apo-Mefloquine to prevent malaria if you have or have had depression or seizures. You should also not take Apo-Mefloquine to prevent malaria if you have had a recent mental illness or problem, including anxiety disorder, schizophrenia (a severe type of mental illness), or psychosis (losing touch with reality).

Apotex Inc. has sent a letter to all pharmacists and travel medicine doctors to inform them of this new safety information. This information is available on the website of the Therapeutic Products Directorate of Health Canada, at the following address:

http://www.hc-sc.gc.ca/hpfb-dgpsa/tpd-dpt/index_advisories_e.html

Pharmacists have been asked to provide patients with a Patient Information Leaflet with each prescription or refill dispensed. You may obtain a copy of the updated Patient Information Leaflet on the Apotex Inc. website at www.apotex.ca.

If you have questions regarding your current Apo-Mefloquine prescription, you are asked to contact your doctor or pharmacist.

The safety of patients remains our first priority. Patients and health care providers may report suspected adverse drug reactions to Apotex Inc., or to Health Canada through the Canadian Adverse Drug Reaction Monitoring Program (CADRMP) at the following addresses:

Apotex Inc.
Pharmacovigilance Division
150 Signet Drive
Weston, Ontario
M9L 1T9
Tel: 1-800-667-4708

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
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/hpfb-dgpsa/tpd-dpt/adverse_e.html
http://www.hc-sc.gc.ca/hpfb-dgpsa/tpd-dpt/adr_guideline_e.html



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If you are a healthcare professional, please [click here](#) for more information.