

PUBLIC COMMUNICATION
Health Canada Endorsed Important Safety Information on the Recall of Depakene® (valproic acid) 500-mg Enteric-Coated Capsules



May 14, 2007

Subject: URGENT PRODUCT RECALL
Voluntary Type I Recall of Depakene® (valproic acid) 500-mg Enteric-Coated Capsules in Canada

Dear Patient:

Abbott Laboratories, Limited (Abbott) and Health Canada are advising the public of a voluntary recall of Depakene® (valproic acid) 500-mg enteric-coated capsules. Depakene® (valproic acid) is a prescription medication used to treat epilepsy. Routine product testing indicated that the product's shelf-life is not as long as marked on the packaging. As a result, a lesser amount of active ingredient may be released. This may result in inadequate seizure control, potentially putting patients at risk for a greater number of seizures.

- Problems with shelf-life of Depakene® (valproic acid) 500-mg enteric-coated capsules may lead to them not working as well as they should, leading to inadequate seizure control.
- Patients currently taking Depakene® (valproic acid) 500-mg enteric-coated capsules should immediately contact their doctor or pharmacist to identify and determine other treatment options.
- Patients should not discontinue Depakene® (valproic acid) 500-mg enteric-coated capsules until they have obtained alternative treatment. Patients should immediately consult their doctor or pharmacist to have alternative treatment identified.

In addition, due to changes in manufacturing availability, Depakene® (valproic acid) 500-mg enteric-coated capsules is permanently discontinued as of May 11, 2007 and will no longer be available in Canada.

No other Depakene® formulation or Abbott product is affected by this action.

Patients must return Depakene® (valproic acid) 500-mg enteric-coated capsules to their pharmacists.

As with any drug product, in order to avoid contaminating ground or municipal water systems, the product should not be flushed down the toilet or sink.

Abbott has sent a letter to Canadian health care professionals notifying them of this important voluntary recall. You may view this letter on the Abbott website at <http://www.abbott.ca>. The Public Warning will be also posted on Health Canada website at http://www.hc-sc.gc.ca/hpfb-dgpsa/tpd-dpt/index_advisories_e.html.

Abbott reiterates its commitment to the health and safety of patients and the delivery of quality products.

Should you have any questions or require additional information regarding the recall of Depakene® (valproic acid) 500-mg enteric-coated capsules, please contact your health care provider.

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 Depakene® (valproic acid) 500-mg enteric-coated capsules should be reported to Abbott or Health Canada at the following addresses:

Abbott Laboratories, Limited
Medical Information Department
8401 Trans-Canada Highway
Saint-Laurent, Quebec H4S 1Z1

Tel : 1-800-567-2226
Fax : (514) 832-7824

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

Toll Free Tel: (866) 234-2345 or Toll Free 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*.