

Health Canada Endorsed Important Safety Information on
Depakene® (valproic acid) 500-mg Enteric-Coated Capsules



May 11, 2007

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

Dear Health Care Professional,

Abbott Laboratories, Limited (Abbott) is advising health care professionals of the immediate voluntary recall of all lots of Depakene® (valproic acid) 500-mg enteric-coated capsules (DIN 00507989) due to stability test failures: routine stability testing has 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.

Depakene® (valproic acid) is indicated as sole or adjunctive therapy in the treatment of simple or complex absence seizures, including petit mal, and is useful in primary generalized seizures with tonic-clonic manifestations. It may also be used adjunctively in patients with multiple seizure types which include either absence or tonic-clonic seizures.

Prescribers:

- Immediately identify and determine alternative treatment options for patients currently taking Depakene® (valproic acid) 500-mg enteric-coated capsules;
- Do not initiate treatment of new patients with Depakene® (valproic acid) 500-mg enteric-coated capsules.

Pharmacists:

- Do not dispense further prescriptions for Depakene® (valproic acid) 500-mg enteric-coated capsules;
- Immediately contact the patients' physician to identify and determine alternative treatment options for all patients currently taking Depakene® (valproic acid) 500-mg enteric-coated capsules;
- **Do not return any Depakene® (valproic acid) 500-mg enteric-coated capsules until contacted by your wholesaler, distributor and/or Abbott Customer Service.**

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.

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

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

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
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

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*.

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 the Abbott Medical Information Department at 1-800-361-7852.

Sincerely,



Tom Koutsavlis, MD, MSc, CSPQ, FRCPC
Medical Director,
Abbott