

**Health Canada Endorsed Important Safety Information on
Lithium Carbonate SR tablets 300 mg strength**



26 October 2009

01.2

Dear Health Care Professional,

Subject: Type II Product Recall of Apo-Lithium Carbonate SR 300 mg strength tablets.

Product	Strength	DIN	Package Type	Lot/Batch Nos.	Expiry date
Apo-Lithium Carbonate SR	300 mg	02266695	Bottles of 100 tablets	HT 9748	2010/03
				HV 7090	2010/05
				HX 9290	2010/07

Apotex Inc., in collaboration with Health Canada, wishes to advise health care professionals that a recall of Apo-Lithium Carbonate SR 300 mg strength tablets was initiated on 20 October 2009 due to stability issues which may have had an impact on the quality of the product. Given the recall, a shortage of sustained release preparation of lithium may occur in which case patients taking Apo-Lithium Carbonate SR 300 mg may need to be switched to an alternate lithium preparation. Alternate lithium options include other sustained release preparations or immediate release preparations. In the event that a patient is switched to an immediate release formulation of lithium carbonate, titration of dose, careful monitoring of lithium blood levels, adverse effects and compliance is advised.

Apo-Lithium Carbonate is indicated in the lithium treatment of manic episodes of manic-depressive illness. Maintenance therapy has been found to be useful in preventing or diminishing the frequency of subsequent relapses in bipolar manic-depressive patients (with a history of mania).¹

- Pharmacists are requested to refer patients to their physicians IMMEDIATELY for alternate therapy if they are unable to fill a patient's prescription with Lithium Carbonate SR 300 mg.
- Physicians are requested to be accessible to their patients who may need to be switched from the sustained release product to an immediate release version.
- In light of the narrow therapeutic index when using lithium, physicians are reminded to titrate lithium doses carefully and to monitor lithium blood levels closely, if and when a change is made to immediate release lithium formulations.

Managing marketed health product-related adverse reactions depend 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. We encourage the reporting of adverse effects to either Apotex Inc. or Health Canada at the following addresses:

¹ Canadian Product Monograph, Apo-Lithium Carbonate SR, 300 mg. Revised November 22, 2005; page 5.

Apotex Inc.
150 Signet Drive
Toronto, ON
M9L 1T9
Tel: 800 667 4708
Fax: 416 401 3819
E-mail: drugsafety@apotex.com

Any suspected adverse reaction can also be reported to:

Canada Vigilance Program
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
CanadaVigilance@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/ar-ei_form-eng.php
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:

Lead Directorate: Health Product and Food Branch Inspectorate (HPFBI)
E-mail: DCVIU_UVCEM@hc-sc.gc.ca
Tel: 1-800-267-9675
Fax: 1-613-946-5636

Sincerely,

Lance Lovelock
Vice President Quality Assurance

Colin D'Cunha MBBS, MHS, FRCPC
Director- Global Pharmacovigilance