

**Health Canada Endorsed Important Safety Information on
ADRENALIN™**



August 12, 2010

Dear Health Care Professional,

**Subject: Risk of Inadvertent Injection of Adrenalin™
(epinephrine chloride 1:1000) Intended for Topical Use**

Erfa Canada Inc. in consultation with Health Canada would like to inform you of important safety information concerning an increased risk of inadvertent injection of topical/nasal Adrenalin™ 1 mg/mL (epinephrine chloride 1:1000) due to the similarity of its packaging to injectable use vials. Epinephrine is used topically as a hemostatic to control superficial bleeding and improve visibility, mainly during surgery.

- The topical epinephrine vial resembles an injectable use vial which permits insertion of a needle and withdrawal of concentrated epinephrine 1:1000 into a parenteral syringe. This can lead to inadvertent injection of a product that may be 10 to 100 times stronger than is intended (e.g., local anesthetic with dilute epinephrine).
- The metal pull tab on the topical epinephrine vial can break preventing the user from pouring out the topical epinephrine. This can lead to withdrawal of the contents into a parenteral syringe.
- Concentrated epinephrine solutions (1:1000) intended for topical use should not be withdrawn into a parenteral syringe as this can lead to inadvertent injection of the solution, resulting in serious cardiovascular events including death.¹

The topical/nasal Adrenalin™ (epinephrine chloride 1:1000) vial has a rubber stopper held in place by a metal ferrule which can lead to the withdrawal of topical epinephrine into a parenteral syringe and if injected can result in serious cardiovascular events including death. There has also been reported difficulty in the removal of the vial's metal ferrule due to the pull tab breaking before the rubber stopper can be removed. This can lead users to withdraw the contents with a parenteral syringe. The withdrawal of concentrated epinephrine 1:1000 (including injectable Adrenalin™ (epinephrine chloride 1:1000) when substituted for the topical product) into a parenteral syringe can lead to inadvertent injection resulting in serious patient harm. The above-mentioned packaging issues augment the risk of serious medication incidents.

Two medication incidents involving the inadvertent injection of concentrated epinephrine (1:1000) have been published by the Institute for Safe Medication Practices Canada (ISMP Canada) in a safety bulletin¹ and several others have also been reported in Canada and the United States including cases with fatal outcome.²

Erfa Canada Inc. in consultation with ISMP Canada is working towards a solution to modify the topical epinephrine vial in order to make it easier to differentiate from an injectable use vial. In the interim, Erfa Canada Inc. will work towards resolving the metal ferrule issue.

Until such time as new packaging is available, good practices should continue to be observed and include: arranging for the pharmacy to pre-package the epinephrine for topical use; labelling of all syringes and containers; keeping medications intended for injection (such as local anesthetics) in their original containers; and only withdrawing injectable medications into a labelled syringe just prior to use.¹ To avoid mix-ups with concentrated epinephrine solutions intended for topical use, epinephrine solutions intended for injection (e.g., local anesthetics with dilute epinephrine) should not be placed in an open container. Discard any unlabelled syringes and containers. More information about practice-related medication incident prevention measures can be obtained from ISMP Canada (Email: info@ismp-canada.org; Phone: 1-866-544-7672). Defective vials can be returned to Ropack/Erfa Canada Inc. c/o Returns 7800 Vauban, Anjou, QC, H1J 2N1.

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 events due to inadvertent injection of topical/nasal Adrenalin™ (epinephrine chloride 1:1000) or other serious or unexpected adverse reactions in patients receiving Adrenalin™ (epinephrine chloride 1:1000) should be reported to Erfa Canada Inc. or Health Canada. Medication incidents can also be reported to ISMP Canada through the Canadian Medication Incident Reporting and Prevention System (<http://www.ismp-canada.org/cmirps.htm>).

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You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

- Report online at www.healthcanada.gc.ca/medeffect
- Call toll-free at 1-866-234-2345
- Complete a Reporting Form and:
 - * Fax toll-free to 1-866-678-6789, or
 - * Mail to: Canada Vigilance Program
Health Canada
Postal Locator 0701E
Ottawa, Ontario K1A 0K9

The Reporting Forms, postage paid labels, and Guidelines can be found on the MedEffect™ Canada Web site in the Adverse Reaction Reporting section (<http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/index-eng.php>). The Reporting Form is also in the *Canadian Compendium of Pharmaceuticals and Specialties*.

For other health product inquiries related to this communication, please contact Health Canada at:

Marketed Health Products Directorate

E-mail: mhpd.dpdc@hc-sc.gc.ca

Telephone: 613-954-6522

Fax: 613-952-7738

To change your mailing address or fax number, contact the Market Authorization Holder (Industry).

original signed by

Simon Soucy

**Vice President
Ergo Canada Inc.**

References:

1. Institute for Safe Medication Practices Canada. ALERT: Fatal outcome after inadvertent injection of epinephrine intended for topical use. ISMP Can Saf Bull. 2009 [cited 2009 Nov 1]; 9(2):1-2. Available from <http://www.ismp-canada.org/download/safetyBulletins/ISMPCSB2009-2-InadvertentInjectionofEpinephrineIntendedforTopicalUse.pdf>

2. Institute for Safe Medication Practices Canada. Risk of tragic error continues in operating rooms. ISMP Can Saf Bull. 2004 [cited 2009 Nov 7]; 4(12):1-2. Available from www.ismp-canada.org/download/safetyBulletins/ISMPCSB2004-12.pdf