

**Health Canada Endorsed Important Safety Information on
Topical Anesthetics**



2009-03-02

Dear Healthcare Provider,

Subject: Association of Topical Anesthetics with Serious Adverse Events

Health Canada, in collaboration with AstraZeneca Canada Inc. and Smith & Nephew Inc., wishes to provide you with important safety information regarding topical anesthetics (e.g. EMLA[®], AMETOP Gel[™] and locally compounded products). In recent years there have been reports of serious adverse events including fatalities that have been associated with excessive topical application of local anesthetics in both adult and pediatric patients.

Canadian cases of serious adverse events associated with topical anesthetics have been reported to Canada Vigilance. Many cases involved self-application by adults of the topical anesthetics to a large surface area of the body in preparation for laser removal of body hair. A few pediatric cases appear to have involved doses within or just above the recommended range. There was a pediatric case with fatal outcome for which information about dosage and possible predisposing conditions was not available.

The risk of serious adverse effects increases with the concentration and the quantity of topical anesthetic used. Some topical anesthetics compounded by pharmacists can be more concentrated than topical anesthetics approved by Health Canada.

- Serious adverse reactions including methemoglobinemia, central nervous system toxicity and cardiovascular collapse have been associated with application of topical anesthetics to large surface areas of the body, often in preparation for laser removal of body hair.
- Patients are more likely to experience serious side effects from a topical anesthetic if they use it on a large area of their body, if they apply it to abraded or diseased skin or if they occlude the treated area with plastic wrap or other dressing.
- Children should be closely observed during and after use of topical anesthetics, as they may be at greater risk than adults for serious adverse events.

Topical anesthetics are generally indicated for dermal analgesia prior to procedures such as vaccinations and minor skin surgery. Use of an occlusive dressing is recommended in the product labeling to facilitate absorption when the application is to intact skin. Topical anesthetics are, however, also being used commonly for dermal analgesia prior to laser removal of body hair. When used for this purpose the drug is sometimes applied in excessive amounts to much larger areas than it would normally be applied and

then covered with plastic wrap to enhance absorption. This combination of the large amount used and the occlusion increases the risk of serious side effects.

Manifestations of systemic toxicity from local anesthetics may include cyanosis, headache, drowsiness, respiratory depression, confusion, convulsions, bradycardia, hypotension and cardiac arrhythmias.

Please refer to topical anesthetic prescribing information for full prescribing, adverse reaction, drug interaction and treatment of overdose information.

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 a topical anesthetic product should be reported to the manufacturer, or to Health Canada at the following addresses:

For EMLA® Products:
AstraZeneca Canada Inc.
1004 Middlegate Road
Mississauga, ON L4Y 1M4
Tel: 1-800-433-0733
Fax: 1-800-267-5743
www.astrazeneca.ca

For AMETOP Gel™:
Smith & Nephew Inc.
2250 Boul. Alfred-Nobel
Saint-Laurent, QC H4S 2C9
Tel: 1-800-463-7439
Fax: 1-800-671-9140
www.smith-nephew.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/alt_formats/hpfb-dgpsa/pdf/medeff/ar-ei_form-eng.pdf
http://www.hc-sc.gc.ca/dhp-mps/medeff/centre-learn-appren/cons_ar-ei_guide-eng.php

For other inquiries related to this communication, please contact Health Canada at:
Marketed Health Products Directorate (MHPD)
E-mail: MHPD_DPSC@hc-sc.gc.ca
Tel: (613)-954-6522
Fax: (613)-952-7738

Any questions from health care professionals regarding EMLA may be directed to the AstraZeneca Medical Information department at 1-800-668-6000 from 8 a.m. to 5 p.m. Monday thru Friday Eastern Standard Time.

Should you have any questions or require additional information regarding the use of AMETOP Gel, please contact Smith & Nephew Inc. at 1-800-463-7439 from 8:30 a.m. to 5:30 p.m. Monday to Friday Eastern Standard Time.

Please contact the appropriate manufacturer with any questions or concerns.

original signed by

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