

PUBLIC COMMUNICATION
Health Canada Endorsed Important Safety Information on
Topical Anesthetics



2009-03-05

Subject: Association of Topical Anesthetics with Serious Side Effects

Health Canada, in collaboration with AstraZeneca Canada Inc. and Smith & Nephew Inc., wishes to alert Canadians to the potential hazards of topical anesthetics (e.g. EMLA®, AMETOP Gel™ and locally compounded products). Topical anesthetics are generally approved for numbing the skin before procedures like vaccinations and minor skin surgery. Topical anesthetics are also being used, often without direct medical supervision, to numb large areas of skin before cosmetic procedures such as laser removal of body hair.

Serious side effects of topical anesthetics have been reported, including seizures, irregular heartbeat and difficulty breathing. In rare instances these side effects have resulted in death. Adults who have experienced these serious side effects used very large amounts of topical anesthetics. After applying the product to their skin, they usually covered the area with plastic wrap to increase the effectiveness of the topical anesthetic. Some infants and children have experienced serious side effects after receiving amounts of topical anesthetics close to the recommended dose.

- Serious side effects have occurred with application of topical anesthetics over large areas of skin often before laser removal of body hair.
- You are more likely to have serious side effects if you apply large amounts of these products to irritated or broken skin or if you apply large amounts of these products and cover the treated area with plastic wrap or other dressing.
- Children should be closely observed during and after use of topical anesthetics, as they are at greater risk than adults for serious side effects.
- If someone using a topical anesthetic shows signs such as weakness, confusion, headache, difficulty breathing, discoloured skin, or any other sign of being unwell, they should receive immediate medical attention.

If you plan to use a topical anesthetic, you should carefully read and follow the product label and/or package insert. An air-tight dressing can be used with some topical anesthetics. If you are not sure about the amount to use or how to apply the product, ask your doctor or pharmacist or other knowledgeable health care professional for guidance.

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 topical anesthetics 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*.

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 regarding EMLA from the public may be directed to the AstraZeneca Medical Information department at 1-800-668-6000 from 8 a.m. to 5 p.m. Monday through Friday, Eastern Standard Time. For media inquiries, please contact AstraZeneca Canada Inc., Corporate Communications at 905-277-7111 from 9:00 a.m. to 5:00 p.m. Monday through 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.

This communication may be found on Health Canada's website at:

<http://www.hc-sc.gc.ca/dhp-mps/medeff/index-eng.php>

or on AstraZeneca's website at:

<http://www.astrazeneca.ca/en/products/>

or on Smith & Nephew's website at:

http://wound.smith-nephew.com/ca_en/

original signed by

Catriona McMahon, MD
Vice-President, Medical Affairs
AstraZeneca Canada Inc.

original signed by

Terry McMahon
Director, Regulatory Affairs and NA Compliance
Officer
Smith & Nephew Inc.

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