

## Excessive Use of Topical Anesthetics Can Be Fatal

### Information from Industry

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February 8, 2007 — The US Food and Drug Administration (FDA) has warned healthcare professionals regarding potential risks associated with unsupervised patient use of topical anesthetic products for cosmetic procedures.

Although topical anesthetic creams, ointments, and gels containing lidocaine, tetracaine, benzocaine, and prilocaine are usually applied in a physician's office prior to medical procedures, their use for cosmetic procedures may be unsupervised by a healthcare professional.

As a result, patients may apply excessive amounts of the topical product to their skin, leading to systemic absorption of the active ingredient and life-threatening adverse events such as arrhythmias and seizures, according to an alert sent this week from MedWatch, the FDA's safety information and adverse event reporting program.

Two cases cited by the FDA in a public health advisory include young women aged 22 and 25 years who applied topical anesthetics with high doses of lidocaine and tetracaine to their legs prior to laser hair removal. As instructed, the women wrapped their legs in plastic wrap to increase the creams' numbing effect. Both women had seizures, fell into comas, and subsequently died from the toxic effects of systemic absorption.

The FDA has also received reports of serious and potentially fatal adverse events such as arrhythmia, seizures, coma, and slowed or stopped breathing after use of anesthetic topical products in children and adults when used for approved and unapproved indications.

Healthcare professionals are advised to prescribe FDA-approved topical anesthetics in the lowest concentration consistent with pain relief goals, and to advise patients regarding their safe use.

Adverse events potentially related to use of topical anesthetic products should be reported to the FDA's MedWatch reporting program by phone at 1-800-FDA-1088, by fax at 1-800-FDA-0178, online at <http://www.fda.gov/medwatch>, or by mail to 5600 Fishers Lane, Rockville, MD 20852-9787.