

FDA Public Health Advisory for Topical Anesthetics

The FDA is aware that lidocaine, a type of topical anesthetic, was studied to see if it may reduce discomfort during breast mammography. During the study, the topical product was spread over a wide area and covered with plastic wrap. Although no serious side-effects were reported in this study, it was not large enough to evaluate whether uncommon but serious reactions could occur with this use. FDA remains concerned about the potential for topical anesthetics to cause serious and life-threatening adverse effects when applied to a large area of skin or when the area of application is covered.

Topical anesthetics work by blocking pain sensation in the skin. Some of the medication in a topical anesthetic can pass through the skin into the blood stream. More of the medication will pass into the blood stream if the topical anesthetic is applied over a large area of the skin, if a large amount is applied, if it is applied to irritated or broken skin, or if the skin temperature increases. Skin temperature can increase during exercise, by covering the skin with a wrap, or with use of a heating pad. Under these circumstances, the amount of anesthetic medication that reaches the blood stream is unpredictable and may be high enough to cause life-threatening adverse effects such as irregular heartbeat, seizures, breathing difficulties, coma and even death.

There are several topical anesthetics available by prescription and over-the-counter. When used appropriately, these products may provide safe and effective pain relief. Before recommending a topical anesthetic for any purpose, doctors should determine if the desired amount of pain relief can be achieved safely with a topical anesthetic, or if a different treatment would be more appropriate. If a topical anesthetic is determined to be the best choice, the lowest needed amount should be prescribed. Patients should speak with their doctor if they are considering using a topical anesthetic before a mammogram.

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