

FDA alerts public about danger of skin numbing products

Agency says that there are serious and life-threatening risks associated with improper use.

The U.S. Food and Drug Administration has issued a Public Health Advisory to alert consumers, patients, health care professionals, and caregivers about potentially serious and life-threatening side effects from the improper use of skin numbing products. The products, also known as topical anaesthetics, are available in over-the-counter (OTC) and prescription forms.

Skin numbing products are used to desensitize nerve endings that lie near the surface of the skin, causing a numbness of the skin. These topical anaesthetics contain anaesthetic drugs such as lidocaine, tetracaine, benzocaine, and prilocaine in a cream, ointment, or gel. When applied to the skin surface, they can be absorbed into the blood stream and, if used improperly, may cause life-threatening side effects, such as irregular heartbeat, seizures, breathing difficulties, coma, or even death.

The FDA has received reports of adverse events and deaths of two women who used topical anaesthetics before laser hair removal. In February 2007, the FDA issued a Public Health Advisory - *Life-Threatening Side Effects with the Use of Skin Products containing Numbing Ingredients for Cosmetic Procedures*, to warn consumers about these products.

Patients for whom an over-the-counter or prescription topical anaesthetic is recommended should consider using a topical anaesthetic that contains the lowest amount possible of medication that will relieve your pain. Also, health care professionals should determine whether adequate pain relief can be safely achieved with a topical anaesthetic, or whether a different treatment would be more appropriate.

The FDA strongly advises consumers not to:

- make heavy application of topical anaesthetic products over large areas of skin;
- use formulations that are stronger or more concentrated than necessary;
- apply these products to irritated or broken skin;
- wrap the treated skin with plastic wrap or other dressings; and
- apply heat from a heating pad to skin treated with these products.

When skin temperature increases, the amount of anaesthetic reaching the blood stream is unpredictable and the risk of life-threatening side effects increases with greater amounts of lidocaine in the blood.

A recently published study in *Radiology* looked at women taking acetaminophen and ibuprofen by mouth versus applying lidocaine gel, a topical anaesthetic, to the skin to decrease discomfort during mammography. The lidocaine gel was applied

to a wide skin surface area and then covered with plastic wrap. There were no serious or life-threatening side effects reported in the study, nor were any reported when FDA discussed the results with the doctor who performed the study. The study results favoured the use of lidocaine as there was significantly less discomfort than with the plain gel or oral acetaminophen or ibuprofen. However, given the life-threatening side effects associated with the use of topical anaesthetics during laser hair removal, FDA is concerned that similar side effects could occur when topical anaesthetics are used during mammography. Further, the study was small and it is possible that a larger study might show different findings.

Patients should talk with their health care professional if they are considering using a topical anaesthetic before a mammogram. The following summarizes advice for patients if a topical anaesthetic is recommended for their use...

Follow these pointers:

- use a topical anaesthetic that contains the lowest strength, and amount, of medication that will relieve the pain;
- apply the topical anaesthetic sparingly and only to the area where pain exists or is expected to occur;
- do not apply the topical anaesthetic to broken or irritated skin;
- ask their healthcare professional what side effects are possible and how to lower their chance of having life-threatening side effects from anaesthetic drugs; and
- be aware that wrapping or covering the skin treated with topical anaesthetics with any type of material or dressing can increase the chance of serious side effects, as can applying heat to the treated area while the medication is still present.

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