Use Caution with Over-the-Counter Creams, Ointments

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Acne, cough due to a cold, athlete's foot, hemorrhoids, itching from insect bites, and minor aches and pains of muscles and joints—these are among the conditions that people treat by applying over-the-counter (OTC) creams and ointments to their skin. The Food and Drug Administration (FDA) urges consumers to keep safety in mind when using such treatments.

"These products are medicines," says Andrea Leonard-Segal, M.D., Director of FDA's Division of Nonprescription Clinical Evaluation in the agency's Center for Drug Evaluation and Research. "Just because they are not in pill form and do not require a doctor's prescription, does not mean that they cannot cause harm if they're overused or misused."

Dr. Segal says that consumers should carefully read and follow the directions for all OTC products, including topical ones. Topical products are those that are applied to certain areas of the skin.

"The medication in creams and ointments can sometimes penetrate the skin and enter the blood stream," she says. "It is important to be aware that the medicines in these

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topical products may cause problems if they are not used as directed." Segal adds, "Sometimes the ingredients in these products can even interact with other medicines you are taking."

Methyl Salicylate

Many athletes use muscle ache creams that contain methyl salicylate. Also known as oil of wintergreen, methyl salicylate is an aspirin-type ingredient of many topical creams that relieves pain. Used correctly, creams containing methyl salicylate can provide temporary relief from minor aches and pains of muscles and joints associated with simple backache, arthritis, strains, bruises and sprains.

As with all medications, misuse of these products can cause harm.

Segal warns that products with methyl salicylate should not be used for more than seven days and should not be applied to wounds or damaged skin. They should not be used under a tight bandage, and contact with eyes should be avoided.

FDA requires the labeling of any drug containing more than 5% methyl salicylate to include warnings that cover such precautions as keeping the product out of children's reach and using the product as directed.

"Always remember to read the Drug Facts Label and any information that is provided inside the package of an over-the-counter product," says Segal. "Keep the labeling so you can refer back to it at a future time. The information provided with the medication tells how to use it properly and what to do if a problem occurs while you are using it."

Compounded Creams

FDA is also concerned about some compounded products offered as creams and ointments.

Traditional pharmacy compounding is a practice in which pharmacists combine, mix, or alter ingredients to create unique medications to meet specific medical needs of individual patients in accordance with prescriptions issued by patients' doctors.

Compounded drugs are not reviewed by FDA for safety and effectiveness, and are not FDA-approved. They can expose patients to unnecessary risks when they are used without proper medical supervision.

FDA normally permits traditional pharmacy compounding. By contrast, some pharmacies behave like drug manufacturers, not traditional compounding pharmacies, because they produce standardized versions of products for general distribution.

In December 2006, FDA warned five firms to stop compounding and distributing topical anesthetic creams that were being marketed for general distribution rather than responding to the unique medical needs of individual patients.

Compounded topical anesthetic creams are often used to lessen pain in procedures such as laser hair removal, tattoos, and skin treatments. They are sometimes dispensed by clinics and spas that provide these procedures, or by pharmacies and doctors' offices.

The compounded topical anesthetics that FDA warned about contain high doses of local anesthetics, including lidocaine, tetracaine, benzocaine, and prilocaine. FDA has warned that when different anesthetics are combined into one product, each anesthetic's potential for harm is increased.

This potential harm may also increase if the product is left on the body for long periods of time or applied to broad areas of the body, particularly if an area is then covered by a bandage, plastic, or other dressing. FDA

For more information

FDA Warns Five Firms to Stop Compounding Topical Anesthetic Creams
www.fda.gov/bbs/topics/NEWS/2006/NEW01516.html

Sports Cream Overdose (Medicine Plus, U.S. Library of Medicine/National Institutes of Health)
www.nlm.nih.gov/medlineplus/ency/article/002583.htm