

## **FDA News**

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### **FDA Approves Updated Labeling with Boxed Warning and Medication Guide for Two Eczema Drugs, Elidel and Protopic**

The Food and Drug Administration (FDA) today announced the approval of updated labeling for two topical eczema drugs, Elidel Cream (pimecrolimus) and Protopic Ointment (tacrolimus). The labeling will be updated with a boxed warning about a possible risk of cancer and a Medication Guide (FDA-approved patient labeling) will be distributed to help ensure that patients using these prescription medicines are aware of this concern. The new labeling also clarifies that these drugs are recommended for use as second-line treatments. This means that other prescription topical medicines should be tried first. Use of these drugs in children under 2 years of age is not recommended.

Eczema or atopic dermatitis is one of the most common skin disorders seen in infants and children, affecting 10 to 15 percent of the childhood population. Although the cause of atopic dermatitis is not known, it is thought that there may be an allergic or immune mediated component. Patients have chronic itching and dry skin, which results in redness and damage to the skin due to rubbing and scratching. Both products are applied to the skin to help control eczema. It is not known exactly how the products work, but they have various effects on the body's immune system.

"We are taking steps to ensure that healthcare providers and patients are aware of the possible long-term risks of these products so that they will be used appropriately", said Dr. Steven Galson, Director of FDA's Center for Drug Evaluation and Research (CDER). "Today's actions are aimed at making sure that health care providers and consumers understand the new warnings and that it is important that these products be used as recommended in the label."

On February 15, 2005, FDA's Pediatric Advisory Committee recommended that the labeling should be updated with a boxed warning and a Medication Guide about the possible cancer risk for these drugs. FDA had issued a Public Health Advisory in March 2005 advising physicians about the possible cancer risk. At the same time, FDA indicated it would ask the sponsors to update the labeling to address this possible risk. Although a causal link has not been established, rare reports of cancer (for example, skin and lymphoma) have been reported in patients who had been receiving these products.

The boxed warning informs healthcare professionals that the long term safety of these drugs has not been established. Although studies are being conducted by the manufacturers of both drugs to try to answer questions about cancer risk, it could be many years before the research is concluded. In the meantime, there is a benefit associated with these drugs when used appropriately. For instance, they may be effective when other prescription topical medications do not work or are not advisable for the patient. The drugs are intended to be used for short periods, but if a patient requires a longer period of treatment, the treatment can be repeated after a period of time off treatment. Patients are advised to call their doctor if symptoms worsen, they develop an infection, or if symptoms do not improve within the six weeks of treatment.

The Medication Guide will provide consumer friendly information to patients about how to use the drugs safely. Pharmacists are required to provide the Medication Guide to patients when dispensing the drug. Patients are advised to read the entire Medication Guide and talk to their healthcare provider if they have further questions.

Novartis manufactures Elidel cream and Astellas Pharma, Inc (formerly Fujisawa Healthcare) is the manufacturer of Protopic ointment.