

WY- DUR

Wyoming Drug Utilization Review Board

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Dear Prescriber:

Pimecrolimus (Elidel®) and tacrolimus (Protopic®) are topical immunosuppressant calcineurin inhibitors indicated for the treatment of eczema by suppressing the immune system. Our database indicates you have prescribed one or both of these agents in the past.

On March 10, 2005, the FDA issued a public health advisory for both of these agents. It is thought that pimecrolimus and tacrolimus may cause an increased risk of some cancers, especially in children. Notably, these cancers include skin cancer, lymphoma and precancerous lesions. There is also data of increased cancer development in animals. While these reports do not necessarily imply causation, caution is warranted.

It may take ten years or longer to determine if use of pimecrolimus or tacrolimus is linked to cancer. Human studies will be conducted by the manufacturers. In the meantime, the FDA advises that pimecrolimus or tacrolimus should be used only as labeled, for patients who have failed treatment with other therapies. The FDA has issued the following guidelines for use of these agents:

- Use Elidel and Protopic only as second-line agents for short-term and intermittent treatment of atopic dermatitis (eczema) in patients unresponsive to, or intolerant of other treatments.
- Avoid use of Elidel and Protopic in children younger than 2 years of age. The effect of Elidel and Protopic on the developing immune system in infants and children is not known. In clinical studies, infants and children younger than 2 years old treated with Elidel had a higher rate of upper respiratory infections than did those treated with placebo cream.
- Use Elidel and Protopic only for short periods of time, not continuously. The long term safety of Elidel and Protopic are unknown.
- Children and adults with a weakened or compromised immune system should not use Elidel or Protopic.
- Use the minimum amount of Elidel or Protopic needed to control the patient's symptoms. In animals, increasing the dose resulted in higher rates of cancer.

Thank you for your attention to this matter.

Sincerely,

Debra S. Devereaux

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- 1) FDA talk paper: FDA issues public health advisory informing health care providers of safety concerns associated with the use of two eczema drugs, elidel and protopic. U.S. Food and Drug Administration [2005 Mar 10]: [1 screen]. Available from: URL: <http://www.fda.gov/bbs/topics/ANSWERS/2005/ANS01343.html>
- 2) In brief: Elidel and Protopic. Med Lett Drugs Ther 2005; 47(1205):25.