**Alert for Healthcare Professionals**

# Pimecrolimus (marketed as Elidel)

## 6/2006: The issues described in this alert have been addressed in product labeling.

**FDA ALERT [3/2005]: The FDA has issued a public health advisory to inform healthcare professionals and patients about a potential cancer risk from use of Elidel (pimecrolimus). This concern is based on information from animal studies, case reports in a small number of patients, and knowledge of how drugs in this class work. It may take human studies of ten years or longer to determine if use of Elidel is linked to cancer. In the meantime, this risk is uncertain, and FDA advises Elidel should be used only as labeled, for patients after other prescription treatments have failed to work or cannot be tolerated.**

*This information reflects FDA's preliminary analysis of data concerning this drug. FDA is considering, but has not reached a final conclusion about, this information. FDA intends to update this sheet when additional information or analyses become available.*

*To report any unexpected adverse or serious events associated with the use of Elidel, please contact the FDA MedWatch program at 1-800-FDA-1088 or http://www.fda.gov/medwatch/report/hcp.htm*

**Recommendations**

Physicians with patients using Elidel, or who are considering prescribing the drug, should consider the following:

- Use Elidel only as **second-line agent** for short-term and intermittent treatment of atopic dermatitis, a form of eczema, in patients unresponsive to, or intolerant of other prescription treatments.
- Avoid use of Elidel in children younger than 2 years of age. The effect of Elidel 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 those treated with placebo cream.
- Use Elidel only for short periods of time, not continuously. The long-term safety of Elidel is unknown.
- Children and adults with a weakened or compromised immune system should not use Elidel.
- Use the minimum amount of Elidel needed to control the patient's symptoms. In animals, increasing the dose resulted in higher rates of cancer.

**Data Summary**

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Although pimecrolimus is not genotoxic and does not interact directly with DNA, it may have a potential to impair local immunosurveillance. Repeat dose studies conducted with topical application of pimecrolimus in mice demonstrated a dose and treatment dependent development of lymphoma. Carcinogenicity studies conducted with oral administration of pimecrolimus in mice demonstrated a dose dependent development of lymphoma and benign thymoma. Carcinogenicity studies conducted with topical administration of pimecrolimus in rats demonstrated development of follicular cell adenoma of the thyroid. Data from a recently conducted oral nine-month monkey study showed a dose-related increase in virus-associated lymphoma following administration of pimecrolimus.

As of December 2004, the FDA had received 10 cases of postmarketing reports linking Elidel with cancer-related adverse events. Four cases occurred in children, 3 of these in children less than 6 years of age. The other 6 cases occurred in adults.

Of the 10 postmarketing cases reporting cancer, 6 described cutaneous tumors, 1 described a lymph node/cutaneous tumor related event, and the locations of 3 others were unreported. Four cases described lymphomas; 5 cases described a variety of tumors, including basal cell carcinoma and squamous cell carcinoma; and 1 case described granulomatous lymphadenitis. The median time until diagnosis after initiation of treatment with Elidel was 90 days, with a range between 1 week and 300 days. Two cases also reported a lymphadenopathy. Two cases were confounded, 1 with the presence of nodules prior to the diagnosis of basal cell carcinoma; and another with a pre-existing condition associated with an increased risk for malignant transformation.

Elidel is sometimes absorbed through the skin, though usually at very low amounts. Occasionally, children who have been treated with Elidel have had measurable blood levels of the drug. The potential for systemic immunosuppression is unknown and the role of Elidel in the development of cancer-related events in the individual postmarketing cases is also uncertain.