

TOPICAL CALCINEURIN INHIBITOR (ELIDEL/PROTOPIC) UPDATE, FEBRUARY 2006

Provided courtesy of:
Children's Memorial Hospital
Division of Pediatric Dermatology
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The U.S. Food and Drug Administration (FDA) recently updated the prescribing information for Protopic and Elidel (also known as "topical calcineurin inhibitors") to include a boxed warning and a medication guide for patients. As a result, you may have some questions for your doctor about Protopic or Elidel. Here is some information about this issue.

- The decision by the FDA to add a black box warning was based on a theoretical risk of lymphoma and skin cancer. As stated in the warning, rare cases of lymphoma and skin cancer have been reported in patients using these drugs. However, no link has been established between the use of Protopic or Elidel and the development of lymphoma or skin cancer.
- Clinical studies in humans (including over 20,000 patients worldwide, and more than 10,000 children) have shown that Protopic or Elidel are safe, without any link between their use and skin cancer or lymphoma. To date, there have not been any significant side effects related to Protopic or Elidel use. The most common side effects include a feeling of warmth or burning at the application site, headaches, cold-like symptoms (such as sore throat and cough), and rarely, viral skin infections.
- Since Protopic and Elidel are applied to the skin, very low amounts enter the bloodstream. In studies, most blood levels of Protopic and Elidel were too low to measure.
- Protopic and Elidel have been shown in human clinical trials to be safe and effective treatments for patients 2 years of age and older with mild to moderate atopic dermatitis. They are not recommended for use in patients under 2 years of age. Only the affected areas of the skin should be treated.
- Protopic and Elidel should not be used continuously for a long period of time. They can be used for short-term treatment, and, intermittently, for chronic treatment as directed by your physician.
- The potential increased sensitivity to the long-term effects of ultraviolet light should also be kept in mind, and good sun protection should be used in children treated with this group of medication.
- Support for the safety of Protopic and Elidel in general has been expressed by many professional associations and societies, including the American Academy of Dermatology (AAD), the American Academy of Asthma, Allergy and Immunology (AAAAI), and the American College of Asthma, Allergy and Immunology (ACAAI), as well as leading groups representing patients and their families, such as the National Eczema Association for Science and Education (NEASE).
- Several studies are underway, and a pediatric registry has been established, to evaluate the long-term safety of Protopic and Elidel in thousands of patients.

PATIENT INFORMATION REGARDING ELIDEL[®] (Pimecrolimus) Cream 1%

The US Food and Drug Administration (FDA) had updated the prescribing information for Elidel Cream 1 %, to include a boxed warning and medication guide. As a result, you may have some questions for your doctor about ELIDEL. In addition to having a conversation with your doctor, here is some additional information about this issue.

- **ELIDEL is an important treatment option your doctor may prescribe if you have not responded to other therapies or when other therapies, such as topical steroids, are not right for you.** You can use ELIDEL on all affected areas of your skin, including your face and neck. You can use ELIDEL for short-term and non-continuous chronic treatment, as directed by your doctor. ELIDEL Cream has been shown in human clinical trials to be safe and effective treatment option for patients aged 2 years and older, with mild to moderate atopic dermatitis (eczema).
- **Why did the FDA add a boxed warning to the product information for ELIDEL?**
The decision made by the FDA was based on a theoretical risk of skin malignancy and lymphoma. As stated in the warning, rare cases of skin malignancy and lymphoma have been reported in patients using ELIDEL. However, no link has been established between ELIDEL use and the development of skin malignancy or lymphoma in those cases.
- **Studies in humans show that there is no link between ELIDEL use and skin malignancy or lymphoma.** In clinical studies involving more than 21,000 patients worldwide, including more than 10,000 children, ELIDEL has been found to be effective and safe. Novartis has several trails underway and a pediatric registry to further evaluate the long-term safety of ELIDEL in thousands of patients.
- **Because ELIDEL Cream is applied to the skin, very low amounts enter the bloodstream.** In studies, most blood levels of ELIDEL were too low to measure.

If you have further questions or concerns, please talk with your doctor or for additional information call Novartis at 888-NOW-NOVA.

The safety of using Elidel Cream for a long period of time is not known. A very small number of people who have used Elidel Cream have had skin cancer or lymphoma. However, a link with the use of Elidel Cream has not been shown.

Because of this:

- ✓ Do not use Elidel Cream continuously for a long time.
- ✓ Use Elidel Cream only on areas of your skin that have eczema.
- ✓ Do not use Elidel Cream on a child under 2 years old.

The most common side effects are feeling of warmth or burning where applied, headaches, cold-like symptoms such as sore throat and cough, and rarely, viral skin infections. Limit sun exposure during treatment, even when Elidel's not on your skin.