

# DallasAllergyImmunology

## Concerns About Elidel and Protopic and Cancer

The Food and Drug Administration (FDA) has recommended that a warning about cancer risk be added to the package inserts for Elidel and Protopic (E/P). This issue has been extensively reported in the popular press. We have carefully reviewed all the available information (including the information on which the FDA recommendation is based) and the FDA's rationale for its recommendation.

### Background

E/P are members of a class of drugs that are potent suppressors of the immune system. This class of drugs has been used for many years to prevent organ transplant rejection. When injected or taken orally, these drugs increase cancer risk in a predictable way. The higher the dose, the greater the risk. (When applied to the skin, entry into the body circulation is poor and very little of the drug enters the blood stream.) The way this works is well understood and the increased risk is for particular kinds of cancer, not for cancer in general. It is possible, by examining cells from a cancer, to tell if the cancer was related to the immunosuppressive effects of the drug or not.

### General Information

Because E/P are so effective for eczema they have been widely used since they came to market. Several million people have used Elidel, Protopic or both. Because having eczema doesn't protect one from other diseases, we expect that some people using E/P will develop diseases that people get such as diabetes, heart disease, arthritis, multiple sclerosis and cancer: they would have gotten these diseases anyway.

### Cancer Cases

Twenty-nine cases of cancer have been reported in patients using E/P. These cases have been critically reviewed by cancer experts. We have examined those reviews. **None of the cancer cases are similar to the kinds of cancer that has been seen in patients receiving high doses of this family of drugs by the oral or IV route.** The possible risk is still there but we believe, based on the reviews of the information available, that there is no evidence, at this time, that E/P has caused cancer.

### Recommendation

Elidel and Protopic have been like a miracle for some patients. We carefully consider the risks and benefits of all treatments for our patients. We do not recommend discontinuing E/P. Parents, however, are the ultimate decision-makers for their children.