



## Patient Information Sheet

### Pimecrolimus Cream (marketed as Elidel)

This is a summary of the most important information about Elidel. For details, talk to your healthcare professional.

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**FDA ALERT [03/ 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 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.*

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#### What is Elidel?

- Elidel is a cream used to treat mild to moderate atopic dermatitis, a form of eczema. It should be used only for a short time. It is not for continuous long-term use.
- **Elidel should not be the first prescription treatment that you try to treat your atopic dermatitis. Use Elidel only after other prescription treatments did not work or you had too many side effects with other drugs.**
- Elidel is approved for adults and children 2 years and older with normal immune systems (not weakened or compromised).

#### Who Should Not Use Elidel?

Do not use if:

- Your child with atopic dermatitis is younger than 2 years
- Your atopic dermatitis is infected
- You have Netherton's Syndrome. This is an inherited condition where the skin is red, itchy, and covered with large coarse scales.
- You are pregnant or breastfeeding, unless directed by your doctor.
- You are allergic to Elidel or any of its ingredients

#### What are The Risks?

*Do not use Elidel as the first prescription treatment for your atopic dermatitis since there are risks of some serious side effects. The following are the major potential risks and side effects of Elidel therapy. However, this list is not complete.*

- **Possible risk of lymph node or skin cancer:** As noted in the FDA Alert, FDA has issued a public health advisory to inform healthcare professionals and patients about a potential cancer risk from use of Elidel. 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. The potential for systemic immunosuppression is unknown and the role of Elidel in the development of the cancer-related events in the individual patient reports is also uncertain at this time. Animal studies have showed that skin tumors formed faster in animals treated with pimecrolimus, the active ingredient in Elidel, and exposed to light. Because of this, you should limit exposure to natural or artificial sunlight, such as sunlamps or tanning beds.
- **Viral infections:** Elidel may increase the chance of getting chicken pox, shingles, skin warts, or other viral infections.
- **Skin irritation:** Elidel's most common side effect is a sensation of warmth or burning where you apply the cream. See your doctor if your reaction is severe, or you have it for more than 1 week.
- **Other side effects** may include headache, throat or nose redness and soreness, flu symptoms, fever, and cough.

#### What Should I Tell My Healthcare Professional?

**Before you start using Elidel**, tell your healthcare professional if:

- You are getting light therapy for your skin (phototherapy, UVA or UVB) or a lot of sun exposure
- You are taking any prescription or nonprescription (over-the-counter) medicine or supplements
- You are using any other skin product
- You are pregnant or planning to get pregnant

**After you start using Elidel**, tell your healthcare professional if:

- Your atopic dermatitis does not get better after 6 weeks of use
- Your atopic dermatitis gets worse

#### How Do I Use Elidel?

- Wash your hands before using Elidel.
- Put a thin layer of Elidel cream on the affected skin twice a day, unless otherwise directed by your doctor. Rub in completely. Use the minimum amount of Elidel necessary.
- Wash your hands after applying Elidel unless you are treating your hands.
- Do not use Elidel under a bandage or wrap that keeps out air.
- Stop using Elidel once your symptoms go away.

Questions? Call Drug Information, 1-888-INFO-FDA (automated) or 301-827-4570  
Druginfo@cder.fda.gov





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- Minimize or avoid exposure to natural or artificial sunlight (tanning beds or UVA/B treatment) while using Elidel, even while Elidel is not on your skin.

**Elidel FDA Approved 2001**  
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