



Patient Information Sheet

Tacrolimus Ointment (marketed as Protopic)

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

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 Protopic (tacrolimus). 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 Protopic is linked to cancer. In the meantime, this risk is uncertain, and FDA advises Protopic 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.

What Is Protopic?

- Protopic is an ointment used to treat moderate to severe atopic dermatitis, a form of eczema. It should be used only for a short time. It is not for continuous long-term use.
- **Protopic should not be the first prescription treatment that you try to treat your atopic dermatitis. Use Protopic only after other prescription treatments did not work or you had too many side effects with other drugs.**
- Protopic is approved for adults and children 2 years and older. Adults can use both strengths of Protopic. Only the 0.03% strength of Protopic is approved for 2 to 15 year olds.

Who Should Not Use Protopic?

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 Protopic or any of its ingredients

What Are The Risks?

Do not use Protopic 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 Protopic 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 about a potential cancer risk from use of Protopic. 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 Protopic in the development of the cancer-related events in the individual patient reports is also uncertain at this. Animal studies have showed that skin tumors formed faster in animals treated with tacrolimus, the active ingredient in Protopic, and exposed to light. Because of this, you should limit exposure to natural or artificial sunlight, such as sunlamps or tanning beds.
- **Viral infections:** Protopic use may increase the chance of getting chicken pox, shingles, or other viral infections.
- **Skin irritation:** Protopic's most common side effects are stinging, soreness, a burning feeling, or itching of the skin. See your doctor if these side effects continue or become a problem. .
- **Other side effects** may include headache, skin redness, and flu-like symptoms.

What Should I Tell My Healthcare Professional?

Before you start using Protopic, 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 Protopic, tell your healthcare professional if:

- Your atopic dermatitis does not get better
- Your atopic dermatitis gets worse within the first few weeks of treatment

How Do I Use Protopic?

- Wash your hands before using Protopic. Be sure your skin is dry. Put a thin layer on the affected skin twice a day, about 12 hours apart. Rub it in completely. Use the minimum amount of Protopic necessary.
- Wash your hands after applying Protopic, unless you are treating your hands.





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- Do not use Protopic under a bandage or wrap that keeps out air. You can wear normal clothing over Protopic.
- Use Protopic only on skin. Do not swallow Protopic.
- Stop using Protopic once your symptoms go away.
- Minimize or avoid exposure to natural or artificial sunlight (tanning beds or UVA/B treatment) while using Protopic even while Protopic is not on your skin.

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