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Pimecrolimus Topical

pronounced as (pim e krow' li mus)

IMPORTANT WARNING:

A small number of patients who used pimecrolimus cream or another similar medication developed skin cancer or lymphoma (cancer in a part of the immune system). There is not enough information available to tell whether pimecrolimus cream caused these patients to develop cancer. Studies of transplant patients and laboratory animals and an understanding of the way pimecrolimus works suggest that there is possibility that people who use pimecrolimus cream have a greater risk of developing cancer. More study is needed to understand this risk.

Follow these directions carefully to decrease the possible risk that you will develop cancer during your treatment with pimecrolimus cream:

- Use pimecrolimus cream only when you have symptoms of eczema. Stop using pimecrolimus cream when your symptoms go away or when your doctor tells you that you should stop. Do not use pimecrolimus cream continuously for a long time.
- Call your doctor if you have used pimecrolimus cream for 6 weeks and your eczema symptoms have not improved. A different medication may be needed.
- Call your doctor if your eczema symptoms come back after your treatment with pimecrolimus cream.
- Apply pimecrolimus cream only to skin that is affected by eczema. Use the smallest amount of cream that is needed to control your symptoms.
- Do not use pimecrolimus cream to treat eczema in children who are younger than 2 years old.
- Tell your doctor if you have or have ever had cancer, especially skin cancer, or any condition that affects your immune system. Ask your doctor if you are not sure if a condition that you have has affected your immune system. Pimecrolimus may not be right for you.
- Protect your skin from real and artificial sunlight during your treatment with pimecrolimus cream. Do not use sun lamps or tanning beds, and do not undergo ultraviolet light therapy. Stay out of the sunlight as much as possible during your treatment, even when the medication is not on your skin. If you need to be outside in the sun, wear loose fitting clothing to protect the treated skin, and ask your doctor about other ways to protect your skin from the sun.

Your doctor or pharmacist will give you the manufacturer's patient information sheet (Medication Guide) when you begin treatment with pimecrolimus and each time you refill your prescription. Read

the information carefully and ask your doctor or pharmacist if you have any questions. You can also visit the Food and Drug Administration (FDA) website (<http://www.fda.gov/Drugs> [<http://www.fda.gov/Drugs>]) or the manufacturer's website to obtain the Medication Guide.

Talk to your doctor about the risks of using pimecrolimus.

Why is this medication prescribed?

Pimecrolimus is used to control the symptoms of eczema (atopic dermatitis; a skin disease that causes the skin to be dry and itchy and to sometimes develop red, scaly rashes). Pimecrolimus is only used to treat patients who cannot use other medications for eczema, or whose symptoms were not controlled by other medications. Pimecrolimus is in a class of medications called topical calcineurin inhibitors. It works by stopping the immune system from producing substances that may cause eczema.

How should this medicine be used?

Pimecrolimus comes as a cream to apply to the skin. It is usually applied twice a day for up to 6 weeks at a time. Follow the directions on your prescription label carefully, and ask your doctor or pharmacist to explain any part you do not understand. Apply pimecrolimus cream exactly as directed. Do not apply more or less of it or apply it more often than prescribed by your doctor.

Pimecrolimus cream is only for use on the skin. Be careful not to get pimecrolimus cream in your eyes or mouth. If you get pimecrolimus cream in your eyes, rinse them with cold water. If you swallow pimecrolimus cream, call your doctor.

To use the cream, follow these steps:

1. Wash your hands with soap and water.
2. Be sure that the skin in the affected area is dry.
3. Apply a thin layer of pimecrolimus cream to all affected areas of your skin. You can apply pimecrolimus to all affected skin surfaces including your head, face, and neck.
4. Rub the cream into your skin gently and completely.
5. Wash your hands with soap and water to remove any leftover pimecrolimus cream. Do not wash your hands if you are treating them with pimecrolimus cream.
6. You may cover the treated areas with normal clothing, but do not use any bandages, dressings, or wraps.
7. Be careful not to wash the cream from affected areas of your skin. Do not swim, shower, or bathe immediately after applying pimecrolimus cream. Ask your doctor if you should apply more pimecrolimus cream after you swim, shower, or bathe.
8. After you apply pimecrolimus cream and allow time for it to be completely absorbed into your skin, you may apply moisturizers, sunscreen, or makeup to the affected area. Ask your doctor about the specific products you plan to use.

Other uses for this medicine

This medication may be prescribed for other uses; ask your doctor or pharmacist for more information.

What special precautions should I follow?

Before using pimecrolimus cream,

- tell your doctor and pharmacist if you are allergic to pimecrolimus or any other medications.
- tell your doctor and pharmacist what prescription and nonprescription medications, vitamins, nutritional supplements, and herbal products you are taking. Be sure to mention any of the following: antifungals such as fluconazole (Diflucan), itraconazole (Sporanox), and ketoconazole (Nizoral); calcium channel blockers such as diltiazem (Cardizem, Dilacor, Tiazac, others), and verapamil (Calan, Isoptin, Verelan); cimetidine (Tagamet); clarithromycin (Biaxin); cyclosporine (Neoral, Sandimmune); danazol (Danocrine); delavirdine (Rescriptor); erythromycin (E.E.S., E-Mycin, Erythrocin); fluoxetine (Prozac, Sarafem); fluvoxamine (Luvox); HIV protease inhibitors such as indinavir (Crixivan), and ritonavir (Norvir); isoniazid (INH, Nydrazid); metronidazole (Flagyl); nefazodone; oral contraceptives (birth control pills); other ointments, creams, or lotions; troleandomycin (TAO); and zafirlukast (Accolate). Your doctor may need to change the doses of your medications or monitor you carefully for side effects.
- tell your doctor if you have or have ever had Netherton's syndrome (an inherited condition that causes the skin to be red, itchy, and scaly), redness and peeling of most of your skin, any other skin disease, or any type of skin infection, especially chicken pox, shingles (a skin infection in people who have had chicken pox in the past), herpes (cold sores), or eczema herpeticum (viral infection that causes fluid filled blisters to form on the skin of people who have eczema). Also tell your doctor if your eczema rash has turned crusty or blistered or if you think that your eczema rash is infected.
- tell your doctor if you are pregnant, plan to become pregnant, or are breast-feeding. If you become pregnant while taking pimecrolimus, call your doctor.
- ask your doctor about the safe use of alcohol during your treatment with pimecrolimus cream. Your face may become flushed or red or feel hot if you drink alcohol during your treatment.
- avoid exposure to chicken pox, shingles and other viruses. If you are exposed to one of these viruses while using pimecrolimus, call your doctor immediately.
- you should know that good skin care and moisturizers may help relieve the dry skin caused by eczema. Talk to your doctor about the moisturizers you should use, and always apply them after applying pimecrolimus cream.

What special dietary instructions should I follow?

Talk to your doctor about eating grapefruit and drinking grapefruit juice while taking this medicine.

What should I do if I forget a dose?

Apply the missed dose as soon as you remember it. However, if it is almost time for the next dose, skip the missed dose and continue your regular dosing schedule. Do not apply extra cream to make up for a missed dose.

What side effects can this medication cause?

Pimecrolimus may cause side effects. Tell your doctor if any of these symptoms are severe or do not go away:

- burning, warmth, stinging, soreness, or redness in the areas where you applied pimecrolimus (call your doctor if this lasts more than 1 week)
- warts, bumps, or other growths on skin
- eye irritation
- headache
- cough
- red, stuffy or runny nose
- nosebleed
- diarrhea
- painful menstrual periods

Some side effects can be serious. If you experience any of the following symptoms, call your doctor immediately:

- sore or red throat
- fever
- flu-like symptoms
- ear pain, discharge, and other signs of infection
- hives
- new or worsening rash
- itching
- swelling of the face, throat, tongue, lips, eyes, hands, feet, ankles, or lower legs
- difficulty breathing or swallowing
- crusting, oozing, blistering or other signs of skin infection
- cold sores
- chicken pox or other blisters
- swollen glands in the neck

Pimecrolimus may cause other side effects. Call your doctor if you have any unusual problems while taking this medication.

If you experience a serious side effect, you or your doctor may send a report to the Food and Drug Administration's (FDA) MedWatch Adverse Event Reporting program online (<http://www.fda.gov/Safety/MedWatch>) or by phone (1-800-332-1088).

What should I know about storage and disposal of this medication?

Keep this medication in the container it came in, tightly closed, and out of reach of children. Store it at room temperature and away from excess heat and moisture (not in the bathroom).

Unneeded medications should be disposed of in special ways to ensure that pets, children, and other people cannot consume them. However, you should not flush this medication down the toilet. Instead, the best way to dispose of your medication is through a medicine take-back program. Talk to your pharmacist or contact your local garbage/recycling department to learn about take-back programs in your community. See the FDA's Safe Disposal of Medicines website (<http://goo.gl/c4Rm4p> [http://goo.gl/c4Rm4p]) for more information if you do not have access to a take-back program.

It is important to keep all medication out of sight and reach of children as many containers (such as weekly pill minders and those for eye drops, creams, patches, and inhalers) are not child-resistant and young children can open them easily. To protect young children from poisoning, always lock safety caps and immediately place the medication in a safe location – one that is up and away and out of their sight and reach. <http://www.upandaway.org> [http://www.upandaway.org]

What other information should I know?

Keep all appointments with your doctor.

Do not let anyone else take your medication. Ask your pharmacist any questions you have about refilling your prescription.

It is important for you to keep a written list of all of the prescription and nonprescription (over-the-counter) medicines you are taking, as well as any products such as vitamins, minerals, or other dietary supplements. You should bring this list with you each time you visit a doctor or if you are admitted to a hospital. It is also important information to carry with you in case of emergencies.

Brand names

- Elidel®

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