

MEDICATION GUIDE

ELIDEL[®] (ÉL-ee-del)

(pimecrolimus)

Cream, 1%

Important: ELIDEL Cream, 1% is for use on the skin only (topical). Do not get ELIDEL Cream, 1% in your eyes, nose, mouth, vagina, or rectum.

What is the most important information I should know about ELIDEL Cream, 1%?

It is not known if ELIDEL Cream, 1% is safe to use for a long period of time. A very small number of people who have used ELIDEL Cream, 1% have developed cancer (for example, skin cancer or lymphoma). But a link that ELIDEL Cream, 1% use caused these cancers has not been shown. Because of this concern:

- Do not use ELIDEL Cream, 1% continuously for a long time.
- Use ELIDEL Cream, 1% only on areas of your skin that have eczema.
- Do not use ELIDEL Cream, 1% on a child under 2 years of age.

What is ELIDEL Cream, 1%?

ELIDEL Cream, 1% is a prescription medicine used on the skin (topical) to treat mild to moderate eczema (atopic dermatitis). ELIDEL Cream, 1% is for adults and children age 2 years and older who do not have a weakened immune system. ELIDEL Cream, 1% is used on the skin for short periods, and if needed, treatment may be repeated with breaks in between. ELIDEL Cream, 1% is for use after other prescription medicines have not worked for you or if your doctor recommends that other prescription medicines should not be used.

It is not known if ELIDEL Cream, 1% is safe and effective in people who have a weakened immune system.

ELIDEL Cream, 1% is not for use in children under 2 years of age.

Who should not use ELIDEL Cream, 1%?

Do not use ELIDEL Cream, 1% if you are allergic to pimecrolimus or any of the ingredients in ELIDEL Cream, 1%. See the end of this Medication Guide for a complete list of ingredients in ELIDEL Cream, 1%.

What should I tell my doctor before using ELIDEL Cream, 1%?

Before using ELIDEL Cream, 1%, tell your doctor about all of your medical conditions, including if you:

- have a skin disease called Netherton's syndrome (a rare inherited condition)
- have any infection on your skin including chicken pox or herpes
- have been told you have a weakened immune system

- are pregnant or plan to become pregnant. It is not known if ELIDEL Cream, 1% will harm your unborn baby.
- are breastfeeding or plan to breastfeed. It is not known if ELIDEL Cream, 1% passes into your breast milk. You and your doctor should decide if you will use ELIDEL Cream, 1% or breastfeed. You should not do both.

Tell your doctor about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Tell your doctor about all the skin medicines and products you use.

Know the medicines you take. Keep a list of them with you to show your doctor and pharmacist each time you get a new medicine.

How should I use ELIDEL Cream, 1%?

- Use ELIDEL Cream, 1% exactly as your doctor tells you to use it.
- Stop ELIDEL Cream, 1% when the signs and symptoms of eczema, such as itching, rash, and redness go away, or as directed by your doctor.
- Wash your hands before using ELIDEL Cream, 1%. If you apply ELIDEL Cream, 1% after a bath or shower, make sure your skin is dry.
- Apply a thin layer of ELIDEL Cream, 1% only to the affected skin areas, two times each day, as directed by your doctor.
- Use the smallest amount of ELIDEL Cream, 1% to help control the signs and symptoms of eczema.
- If you apply ELIDEL Cream, 1% to another person, or if you have eczema and are not treating your hands, it is important for you to wash your hands with soap and water after applying ELIDEL Cream, 1%. This should remove any cream left on your hands.
- Do not bathe, shower or swim right after applying ELIDEL Cream, 1%. This could wash off the cream.
- You can use moisturizers with ELIDEL Cream, 1%. Ask your doctor first about the products that are right for you. People with eczema can have very dry skin, so it is important to keep up good skin care practices. If you use moisturizers, apply them after ELIDEL Cream, 1%.
- **Call your doctor if your symptoms get worse with ELIDEL Cream, 1% or your symptoms do not improve after 6 weeks of treatment.**

What should I avoid while using ELIDEL Cream, 1%?

- You should not use sun lamps, tanning beds, or get treatment with ultraviolet light therapy during treatment with ELIDEL Cream, 1%.
- Limit your time in the sun during treatment with ELIDEL Cream, 1% even when the medicine is not on your skin. If you need to be outdoors after applying ELIDEL Cream, 1%, wear loose fitting clothing that protects the treated area from the sun. Ask your doctor what other types of protection from the sun you

should use. It is not known how ELIDEL Cream, 1% may affect your skin with exposure to ultraviolet light.

- Do not cover the skin being treated with bandages, dressings or wraps. You can wear normal clothing.
- ELIDEL Cream, 1% is for use on the skin only. Do not get ELIDEL Cream, 1% in your eyes, nose, mouth, vagina, or rectum (mucous membranes). If you get ELIDEL Cream, 1% in any of these areas, burning or irritation can happen. Wipe off any ELIDEL Cream, 1% from the affected area and then rinse the area well with cold water.
- Do not swallow ELIDEL Cream, 1%. If you do, call your doctor.
 - Avoid using ELIDEL Cream, 1% on skin areas that have cancers or pre-cancers.

What are the possible side effects of ELIDEL Cream, 1%?

ELIDEL Cream, 1% may cause serious side effects.

- See “What is the most important information I should know about ELIDEL Cream, 1%?”
- The most common side effect at the skin application site is burning or a feeling of warmth. These side effects are usually mild or moderate, happen during the first few days of treatment, and usually clear up in a few days.

Other common side effects include:

- headache
- common cold or stuffy nose, sore throat
- cough
- flu (influenza)
- fever
- viral infection. Some people may get viral skin infections (like cold sores, chicken pox, shingles, or warts) or swollen lymph nodes (glands).

Tell your doctor if you get a skin infection or if you have any side effect (for example, swollen glands) that bothers you or that does not go away.

These are not all the possible side effects with ELIDEL Cream, 1%. Ask your doctor or pharmacist for more information.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store ELIDEL Cream, 1%?

- Store ELIDEL Cream, 1% at room temperature between 68° to 77°F (20° to 25°C).
- Do not freeze ELIDEL Cream, 1%.

Keep ELIDEL Cream, 1% and all medicines out of the reach of children.

General information about the safe and effective use of ELIDEL Cream, 1%

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use ELIDEL Cream, 1% for conditions other than which it was prescribed. Do not give ELIDEL Cream, 1% to other people even if they have the same symptoms you have. It may harm them.

You can ask your doctor or pharmacist for information about ELIDEL Cream, 1% that is written for health professionals.

For more information, go to www.Elidel.com or call 1-800-321-4576.

What are the ingredients in ELIDEL Cream, 1%?

Active ingredient: pimecrolimus

Inactive ingredients: benzyl alcohol, cetyl alcohol, citric acid anhydrous, mono- and di-glycerides, oleyl alcohol, propylene glycol, sodium cetostearyl sulphate, sodium hydroxide, stearyl alcohol, triglycerides, and water

This Medication Guide has been approved by the U.S. Food and Drug Administration.

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