

Medication Guide

ELIDEL[®] [ÉL-ee-del] (pimecrolimus) Cream 1%

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

Read the Medication Guide that comes with ELIDEL Cream before you or a family member start using it and each time you refill your prescription. There may be new information. This Medication Guide does not take the place of talking with your doctor about your medical condition or treatment. If you have any questions about ELIDEL Cream, ask your doctor or pharmacist.

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

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

Because of this concern:

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

What is ELIDEL Cream?

ELIDEL Cream is a prescription medicine used on the skin (topical) to treat eczema (atopic dermatitis). ELIDEL Cream is in a class of medicines called topical calcineurin inhibitors. ELIDEL Cream is for adults and children age 2 years and older who do not have a weakened immune system. ELIDEL Cream is used on the skin for short periods, and if needed, treatment may be repeated with breaks in between. ELIDEL Cream 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 is safe and effective in people who have a weakened immune system.

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

Who should not use ELIDEL Cream?

Do not use ELIDEL Cream:

- if you are allergic to ELIDEL Cream or anything in it. See the end of this Medication Guide for a complete list of ingredients in ELIDEL Cream.

What should I tell my doctor before starting ELIDEL Cream?

Before you start using ELIDEL Cream, 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, breastfeeding, or planning to become pregnant.

Tell your doctor about all the medicines you take including prescription and nonprescription 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?

- Use ELIDEL Cream exactly as prescribed.
- Use ELIDEL Cream only on areas of your skin that have eczema.
- Use ELIDEL Cream for short periods, and if needed, treatment may be repeated with breaks in between.
- Stop ELIDEL Cream when the signs and symptoms of eczema, such as itching, rash, and redness go away, or as directed by your doctor.
- Follow your doctor's advice if symptoms of eczema return after a treatment with ELIDEL Cream.
- Call your doctor if:
 - your symptoms get worse with ELIDEL Cream
 - you get an infection on your skin
 - your symptoms do not improve after 6 weeks of treatment. Sometimes other skin diseases can look like eczema.

To apply ELIDEL Cream:

Read and carefully follow the directions below.

- Wash your hands before using ELIDEL Cream. If you apply ELIDEL Cream after a bath or shower, make sure your skin is dry.
- Apply a thin layer of ELIDEL Cream only to the affected skin areas, two times each day, as directed by your doctor.
- Use the smallest amount of ELIDEL Cream needed to control the signs and symptoms of eczema.
- If you apply ELIDEL Cream 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. This should remove any cream left on your hands.
- Do not bathe, shower or swim right after applying ELIDEL Cream. This could wash off the cream.
- You can use moisturizers with ELIDEL Cream. Make sure you check with 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.

What should I avoid while using ELIDEL Cream?

- You should not use sun lamps, tanning beds, or get treatment with ultraviolet light therapy during treatment with ELIDEL Cream.
- Limit your time in the sun during treatment with ELIDEL Cream even when the medicine is not on your skin. If you need to be outdoors after applying ELIDEL Cream, 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 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 is for use on the skin only. Do not get ELIDEL Cream in your eyes, nose, mouth, vagina, or rectum (mucous membranes). If you get ELIDEL Cream in any of these areas, burning or irritation can happen. Wipe off any ELIDEL Cream from the affected area and then rinse the area well with cold water.
 - Do not swallow ELIDEL Cream. If you do, call your doctor.
 - Avoid using ELIDEL Cream on skin areas that have cancers or pre-cancers.

What are the possible side effects of ELIDEL Cream?

ELIDEL Cream may cause serious side effects. A very small number of people who have used ELIDEL Cream have gotten cancer (for example, skin cancer or lymphoma). But, a link that ELIDEL Cream caused these cancers has not been shown.

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. Call your doctor if the burning feeling is severe or lasts for more than 1 week.

Other side effects include headache, common cold or stuffy nose, sore throat, influenza, fever, viral infection, and cough. 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 have 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. For more information, ask your doctor or pharmacist.

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?

- Store ELIDEL Cream at room temperature between 59° to 86°F (15° to 30°C).
- **Keep ELIDEL Cream and all medicines out of the reach of children.**

General advice about ELIDEL Cream

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Use ELIDEL Cream only for the condition for which it was prescribed. Do not give ELIDEL Cream to other people even if they have the same symptoms you have, as it may not be right for them.

This Medication Guide summarizes the most important information about ELIDEL Cream. If you would like more information, talk with your doctor.

Your doctor or pharmacist can give you information about ELIDEL Cream that is written for health care professionals. For more information, you can also visit the Novartis Internet site at www.elidel.com or call the ELIDEL Cream help line at 877-4 ELIDEL (877-435-4335).

What are the ingredients in ELIDEL Cream?

Active ingredient: pimecrolimus

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

Manufactured by:

Novartis Pharma Produktions GmbH

Wehr, Germany

Distributed by:

Novartis Pharmaceuticals Corp.

East Hanover, New Jersey 07936

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

REV. July 2010

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PRINCIPAL DISPLAY PANEL

Package Label – 30 g

Rx Only NDC 0078-0375-46

ELIDEL® (pimecrolimus) cream 1%

30 g

FOR DERMATOLOGIC USE ONLY. NOT FOR OPHTHALMIC USE.

Each gram contains 10 mg of pimecrolimus