

CONSUMER INFORMATION

Pr **ELIDEL***
(Pimecrolimus)

This leaflet is part III of a three-part "Product Monograph" published when ELIDEL* was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about ELIDEL*. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION

What the medication is used for:

ELIDEL* is a non-steroid prescription medicine that is used to treat eczema (atopic dermatitis) in adults and children age 2 years and older. ELIDEL* is for use on the skin only and should be used only after other therapies have been shown to be ineffective or unsuitable. You should use ELIDEL* as prescribed by your doctor. It should be used for short or intermittent long periods of treatment, as directed by your doctor. Intermittent means starting and stopping repeatedly as directed by your doctor. You should stop using ELIDEL* when signs and symptoms resolve and be instructed by your physician on what actions to take if symptoms recur. ELIDEL* can be applied to all affected areas of the skin including the face and neck.

When it should not be used:

Do not use ELIDEL* if you:

- are breast-feeding or pregnant, unless your doctor determines it is clearly necessary to use ELIDEL*.
- are allergic to any ingredients of ELIDEL*. Speak with your doctor if you have had allergic reactions in the past.
- have any skin infections at the site to be treated; or have a viral infection of your skin, such as chickenpox or herpes. If your skin becomes infected, see your doctor.
- are immunocompromised (have any problems with your immune system).

Contact your doctor or pharmacist if you have any questions

What the medicinal ingredient is:

The active substance in ELIDEL* Cream is pimecrolimus.

What the important nonmedicinal ingredients are:

ELIDEL* also contains benzyl alcohol, cetyl alcohol, citric acid, mono- and di-glycerides, oleyl alcohol, propylene glycol, sodium cetostearyl sulphate, sodium hydroxide, stearyl alcohol, triglycerides, and water.

For a full listing of nonmedicinal ingredients see Part 1 of the product monograph.

What dosage forms it comes in:

ELIDEL* is a 1% cream, available in tubes of 30, 60 and 100 grams.

WARNINGS AND PRECAUTIONS

Long-term safety of topical calcineurin inhibitors (a new class of eczema medication that includes ELIDEL* has not been established. Although a link has not been shown, rare cases of skin malignancy and lymphoma have been reported in patients treated with topical calcineurin inhibitors, including ELIDEL* Cream 1%.

Therefore:

- **Continuous long-term use of ELIDEL* Cream 1% should be avoided, and application limited to areas of the skin with eczema.**
- **ELIDEL* Cream 1% is not indicated in children less than 2 years of age.**

BEFORE you use ELIDEL* talk to your doctor or pharmacist if you are:

- using any other prescription medicines.
- receiving any form of light therapy (phototherapy or UV) for your skin.
- using any medicine for which a prescription is not required, or any natural/herbal remedies.
- using any other type of skin product.
- pregnant, or planning to become pregnant, or breast-feeding.

INTERACTIONS WITH THIS MEDICATION

Be sure to check with your doctor or pharmacist before you start taking any new medicines while using ELIDEL*.

Before you use any other ointments, lotions, or creams on your skin, discuss it with your doctor or pharmacist.

PROPER USE OF THIS MEDICATION

How Do I use ELIDEL*?

-ELIDEL* is for external use only. Do not use it in your nose, eyes or mouth. If your hands are being treated, avoid accidental transfer to these areas. If accidentally applied to the nose, eyes or mouth, the cream should be thoroughly wiped off and rinsed well with water.

- Wash and dry your hands before applying ELIDEL*.

-If your hands are not being treated, wash your hands with soap and water after applying ELIDEL*.

- Apply a thin layer of ELIDEL* to sufficiently cover all skin areas that your doctor has diagnosed as eczema. Try to cover the affected areas completely.

- ELIDEL* should be applied twice a day, about 12 hours apart.

- Do not cover the skin being treated with bandages, dressings, or wraps. However, you can wear normal clothing.

- Do not bathe, shower or swim right after applying ELIDEL*, this could wash off the cream.
- Before applying ELIDEL* after a bath or shower, be sure your skin is completely dry.

How Long Should I Use ELIDEL*?

ELIDEL* usually begins to provide relief from the symptoms of eczema within 1 week. It is important to use ELIDEL* as instructed by your doctor.

If you do not notice an improvement in your eczema within the first 3 weeks of treatment or if your eczema gets worse, you should stop using ELIDEL* and talk to your doctor.

What Should I Avoid While Using ELIDEL*?

Avoid sunlight and sun lamps, tanning salons, and treatment with UVA or UVB light. If you need to be outdoors after applying ELIDEL*, wear clothing that protects the treated area from the sun. In addition, you should ask your doctor what other type of protection from the sun you should use.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

The most common side effects of ELIDEL* are a burning feeling or a sensation of warmth at the site of application. These side effects are usually mild to moderate, occurring within 5 days of treatment, and usually cleared up in the first few days of using ELIDEL*. See your doctor if an application site reaction is severe or persists for more than 1 week.

Other common side effects include headache, and with long-term intermittent use, nasopharyngitis (nose and throat infection) and flu-like symptoms (common cold, congestion, upper respiratory infection), fever, viral infection, and cough. Some people may get herpes skin infections (like cold sores, chickenpox, or shingles), warts, or swollen lymph nodes (glands).

Rarely, facial flushing or skin irritations (e.g. rash, burning, itching or swelling) can occur in patients who drink alcohol while using ELIDEL* 1% cream.

Skin discoloration has been rarely reported.

Some side effects could be serious

Rare: Swelling and pain [eg face], skin rashes or hives (signs of allergic reaction).

Very rare: Sudden wheezing and chest pain or tightening, swelling of eyelids, face or lips (signs of a serious allergic reaction called anaphylactic reaction).

If you experience any of these symptoms after using ELIDEL* cream, stop using the cream and tell your doctor immediately

See your doctor if side effects continue or become a problem.

This is not a complete list of side effects. For any unexpected effects while taking ELIDEL*, contact your doctor or pharmacist.

REPORTING SUSPECTED SIDE EFFECTS

To monitor drug safety, Health Canada collects information on serious and unexpected effects of drugs . If you suspect you have had a serious or unexpected reaction to this drug you may notify Health Canada by:

toll-free telephone: 866-234-2345
 toll-free fax 866-678-6789
 By email: cadrmpp@hc-sc.gc.ca

By regular mail:
National AR Centre
Marketed Health Products Safety and Effectiveness
Information Division
Marketed Health Products Directorate
Tunney’s Pasture, AL 0701C
Ottawa ON K1A 0K9

NOTE: Before contacting Health Canada, you should contact your physician or pharmacist.

HOW TO STORE IT

The cream should be stored at room temperature (15°C - 30°C). Do not freeze the cream. After opening, the contents should be used within 12 months.

Keep ELIDEL* out of the reach of children.

MORE INFORMATION

This document plus the product monograph, prepared for health professionals can be found at:
<http://www.novartis.ca>

or by contacting the sponsor, Novartis Pharmaceuticals Canada Inc., at: 1-800-363-8883

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