



Patient package insert according to Pharmacists' Regulations (Preparations) – 1986

This medicine can be sold with a physician's prescription only

Elidel® Cream 1%

Each gram of cream contains Pimecrolimus 10 mg.

Inactive ingredients and allergens in the medicine – see section 6 "Additional information" and in section 2 "Important information about some of the ingredients of the medicine".

Read this entire leaflet carefully before using the medicine. This leaflet contains concise information about the medicine. If you have any further questions, ask the doctor or pharmacist.

This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if you think that their medical condition is similar to yours.

1. What is the medicine intended for?

The topical preparation is indicated for the treatment of atopic dermatitis (eczema) in infants (3 months of age and above), children, adolescents and adults who did not respond to or could not be treated with topical corticosteroids.

Therapeutic group:

Elidel cream is a non-steroid medication that specifically treats inflammation of the skin and belongs to a class of medicines called topical calcineurin inhibitors. It works in the cells in the skin that cause the inflammation and the characteristic redness and itching of eczema.

2. Before using the medicine

Do not use the medicine if:

- You are hypersensitive (allergic) to the active ingredient (Pimecrolimus), other macrolactams or to any of the other ingredients this medicine contains (see section 6).

Special warnings regarding the use of the medicine

Before the treatment with Elidel, tell the doctor if:

- You have a **weakened immune system** (immuno-compromised) whatever the cause.
- Your skin is infected. Your doctor may ask you to use an appropriate medicine to treat the infection. When the infection at treatment sites is cleared, treatment with **Elidel** can be started. If your skin becomes infected during treatment with **Elidel**, you should inform your doctor. Your doctor may ask you to stop using **Elidel** until the infection has been adequately controlled.
- You have erythroderma (redness of almost the entire body) or a skin condition called Netherton's syndrome.
- You have **skin malignant tumours**.

Additional warnings

- Do not smoke or go near naked flames - risk of severe burns. Fabric (clothing, bedding, dressings etc.) that has been in contact with this medicine burns more easily and is a fire hazard. Washing clothing and bedding may reduce medicine build-up but not totally remove it.
- **Use Elidel only to treat atopic dermatitis.** Do not use for other skin conditions.

- **Elidel cream is for external use only.** Do not use it in your nose, eyes or mouth. If accidentally applied to these areas, the cream should be thoroughly wiped off and/or rinsed with water. You should take care not to swallow it, or to accidentally transfer it into your mouth when, for example, it is applied to the hands.
- **Do not apply the cream to areas of the skin affected by active viral infection** such as cold sores (herpes simplex) or chicken pox.
- **Elidel** may be associated with an increased risk of a severe herpes simplex skin infection (eczema herpeticum). Therefore if you develop **painful sores** anywhere on your body, tell your doctor immediately. You should stop using **Elidel** until the infection has cleared.
- **Elidel** may cause reactions at the application site such as a feeling of warmth and/or a burning sensation. These reactions are usually mild and last only for a short time. Tell your doctor immediately if you have a severe reaction to **Elidel**.
- While using **Elidel**, do not cover the treated skin with bandages, dressings or wraps. However, you can still wear normal clothing.
- **Avoid excessive exposure to sunlight**, sun lamps and tanning beds during treatment with **Elidel**. If you are outdoors after applying **Elidel**, wear loose fitting clothing, use appropriate sunscreen products and minimise the amount of time you spend in the sun.
- If your **lymph nodes become swollen** during treatment with **Elidel**, tell your doctor.

Children

The use of **Elidel** in patients under 3 months of age is not recommended.

Drug interactions

If you are taking, have recently taken or might take other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist.

- Application of the medicine to **vaccination sites** is not recommended, as long as local reactions persist.
- If you have extensive eczema, you may need to stop using **Elidel** before having any **vaccinations**. Your doctor will tell you if this is necessary.
- **Elidel** should not be used at the same time as **ultraviolet light treatments** (such as UVA, PUVA, UVB) or systemic immunosuppressive medicines (such as azathioprine or ciclosporin).
- Interactions with other medicines are unlikely to occur.

Use of Elidel and alcohol consumption

In rare cases, you may experience flushing, rash, burning sensation, itching or swelling shortly after drinking alcohol.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to become pregnant, consult a doctor or pharmacist before using this medicine. You should not use **Elidel** if you are pregnant.

It is not known whether the active substance in **Elidel** passes into the milk after application to the skin. Do not apply **Elidel** to the breasts if breastfeeding.

Driving and using machines

Elidel has no known effect on the ability to drive or use machines.

Important information about some of the ingredients of the medicine

The medicine contains:

- Cetyl alcohol and stearyl alcohol which may cause local skin reactions (e.g. contact dermatitis).
- Benzyl alcohol (10 mg per 1 g cream), which may cause allergic reactions and mild local irritation.
- Propylene glycol (E 1520) (50 mg per 1 g cream) which may cause skin irritation.

3. How to use the medicine?

Always use the medicine according to the doctor's instructions. Check with the doctor or pharmacist if you are not sure about the dosage and the manner of treatment with the medicine.

The dosage and manner of treatment will be determined by the doctor only.

The cream should usually be applied twice daily, morning and evening. Stop **Elidel** as soon as signs and symptoms of eczema have disappeared. If signs and symptoms return, you should start using **Elidel** again.

In the long-term treatment, begin using **Elidel** as soon as you notice signs of eczema. This helps to prevent progression to severe flare-ups.

Consult your doctor if no improvement occurs after 6 weeks. Sometimes other skin conditions might look similar to eczema.

Do not exceed the recommended dose.

The cream may be applied to all areas of the skin, including the head, face, neck and skin folds. Apply the cream only to the area affected with eczema.

In the event of recurrence of eczema symptoms after treatment with the medicine, consult the attending doctor.

Method of use

- Wash and dry your hands.
- Open the tube (when using the tube for the first time, open the seal by using the spike at the top of the cap).
- Squeeze the cream out of the tube onto your finger.
- Apply a thin layer of cream so that the affected area will be covered entirely.
- Rub the cream in gently until it is completely absorbed.
- Replace the cap on the tube.
- Wash your hands after the application (unless they are the area being treated with the cream).

Moisturizers can be applied immediately after using **Elidel**. However, after bathing, moisturizers should be applied before using **Elidel**.

Do not swallow! This medicine is intended for external use only.

If you apply more Elidel than you should

If you accidentally applied a larger amount than necessary, wipe off the excess cream.

If you accidentally swallow some Elidel

If you or someone else accidentally swallowed **Elidel**, tell your doctor immediately.

If you forget to use Elidel

If you forgot to apply the cream at the specified time, apply a dose as soon as you remember and continue to apply at the regularly specified times. Unless it is almost time for your next application. Do not apply extra cream to make up for a missed dose.

Continue with the treatment as recommended by the doctor. Even if there is an improvement in your health, do not stop treatment with the medicine without consulting the doctor or pharmacist.

Do not take medicines in the dark! Check the label and the dose each time you take a medicine. Wear glasses if you need them.

If you have further questions on the use of this medicine, consult the doctor or pharmacist.

4. Side effects

Like any medicine, the use of **Elidel** may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not suffer from any of them.

The most common side effects of **Elidel** are reactions (such as discomfort) at the application site. Such reactions are generally mild/moderate, occur early in treatment and last only for a short time.

Some effects could be serious

Stop applying the cream and contact your doctor immediately at the occurrence of:

Rare side effects (effects that occur in 1-10 out of 10,000 users):

- *angioedema* - the signs include itching, hives (urticaria), red marks on the hands, feet and throat, swelling of the throat and tongue, swelling around the eyes and lips, difficulty breathing and swallowing.

Very rare side effects (effects that occur in less than one in 10,000 users):

- *anaphylactic reaction* - skin rash including red itchy skin, swelling of the hands, feet, ankles, face, lips, mouth or throat (these symptoms also describe angioedema and may cause difficulty in swallowing or breathing) and you may feel you are going to faint.

Other side effects:

Very common side effects (effects that occur in more than 1 in 10 users):

- A feeling of warmth and/or burning at the application site.

Common side effects (effects that occur in 1-10 out of 100 users):

- Irritation, itching and reddening of the skin where the cream has been applied.
- Skin infections (such as folliculitis).

Uncommon side effects (effects that occur in 1-10 out of 1,000 users):

- Skin infections such as impetigo (a bacterial skin infection), cold sores (herpes simplex), shingles (herpes zoster), herpes simplex dermatitis (eczema herpeticum), molluscum contagiosum (a viral skin infection), warts and furuncles (boils).
- Application site reactions such as rash, pain, prickling sensation, slight scaling of the skin, dryness, swelling and worsening of eczema symptoms.

Rare side effects (effects that occur in 1-10 out of 10,000 users):

- Flushing, rash, burning sensation, itching or swelling shortly after drinking alcohol.
- Changes in the skin color (becomes darker or lighter than the surrounding skin).

Cases of cancer, including cancer of the lymph glands or skin, have been reported in patients using **Elidel**.

Cases of enlarged lymph glands have been reported in patients using **Elidel**. However, a link to the treatment with **Elidel** has not been established.

If a side effect occurs, if one of the side effects worsens or if you suffer from a side effect not mentioned in this leaflet, consult the doctor.

Side effects can be reported to the Ministry of Health via the link "דיווח על תופעות לוואי עקב טיפול תרופתי" found on the homepage of the Ministry of Health website (www.health.gov.il) directing to the online form for reporting side effects or via the link: <https://sideeffects.health.gov.il>

5. How to store the medicine?

- Avoid poisoning! This medicine and any other medicine must be stored in a closed place out of the reach and sight of children and/or infants to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the doctor.
- Do not use the medicine after the expiry date (EXP) stated on the package. The expiry date refers to the last day of that month.
- Once opened, the tube should be used within 12 months. You may find it helpful to write the date you opened the tube in the space provided on the package.
- **Storage conditions:** Store below 25°C. Do not freeze. Store in the original package. Keep the tube tightly closed.
- Do not throw away any medicines via wastewater or household waste. Ask the pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Additional information

In addition to the active ingredient, the medicine also contains:

Water (purified), triglycerides, oleyl alcohol, propylene glycol, cetyl alcohol, stearyl alcohol, mono- and di-glycerides, benzyl alcohol, sodium cetostearyl sulphate, citric acid (anhydrous), sodium hydroxide.

What the medicine looks like and what the package contains:

Elidel is a whitish, odourless, non-staining and easily spreadable cream.

Approved package sizes: 15, 30 and 100 grams per package.

Not all package sizes may be marketed.

Revised in November 2024 according to MOH guidelines.

Drug registration number at the national drug registry of the Ministry of Health:

126-12-30517-01

Manufacturer and registration holder:

Dexcel Ltd., 1 Dexcel St., Or Akiva 3060000, Israel