

PACKAGE LEAFLET: INFORMATION FOR THE USER

Elidel 10 mg/g Cream

pimecrolimus

Read all of this leaflet carefully before you start using Elidel cream

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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1. WHAT ELIDEL CREAM IS AND WHAT IT IS USED FOR

Elidel cream contains a medicine called pimecrolimus. It does not contain any steroids. Elidel cream specifically treats an inflammation of the skin called atopic dermatitis (eczema). It works in the cells in the skin that cause the inflammation and characteristic redness and itching of eczema.

The cream is used to treat signs and symptoms of mild or moderate eczema (e.g. redness and itch) in children (aged 2 years and above), teenagers and adults. When used to treat early signs and symptoms it can prevent progression to severe flare-ups.

Elidel cream is for use only after other prescription medicines or emollients have not worked for you or if your doctor recommends that other prescription medicines should not be used.

2. BEFORE YOU USE ELIDEL CREAM

Carefully follow all instructions given to you by your doctor.
Read the following information before you use Elidel cream.

Do not use Elidel cream

- If you are **allergic** (hypersensitive) to pimecrolimus or any of the other ingredients of Elidel cream.

Take special care with Elidel cream

Elidel is not approved for children younger than 2 years of age. Therefore it should not be used in this age group. Please consult your doctor.

Elidel cream is only to be used for 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.

If your skin is infected, check with your doctor before using Elidel. 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.

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.

If you are 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 you have erythroderma (redness of almost the entire body) or a skin condition called Netherton's syndrome, speak to your doctor before you start using Elidel .

Also speak to your doctor before using Elidel if you have any **skin malignancies (tumours)** or if you have a **weakened immune system** (immuno-compromised) whatever the cause.

If your **lymph nodes become swollen** during treatment with Elidel cream, tell your doctor.

Pregnancy and breast-feeding

Tell your doctor before starting treatment with Elidel if you are pregnant or think that you may be pregnant. You should not use Elidel if you are pregnant.

Tell your doctor if you are breast-feeding before using Elidel or any other medicines. 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 breast-feeding.

Using other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

If you have extensive eczema, you may need to stop using Elidel before having any **vaccinations**. Your doctor will be able to 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 cyclosporin).

Interactions with other medicines that you take are unlikely to occur.

Driving and using machines

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

3. HOW TO APPLY ELIDEL CREAM

Always use Elidel exactly as your doctor has instructed. Please check with your doctor or pharmacist if you have any questions.

You can use Elidel on all skin areas, including the head, face and neck and in the folds of the skin.

Apply the cream as follows:

- Wash and dry your hands.
- Open the tube (the first time you use the tube you will need to break the seal using the spike in the top of the cap).
- Squeeze the cream onto your finger.
- Apply a thin layer of Elidel and completely cover the affected skin.
- Apply only on areas affected with eczema
- Rub in gently and fully.
- Replace the cap on the tube.

The cream should be applied twice daily, for instance once in the morning and once in the evening. You can use moisturisers (emollients) with Elidel. If you use moisturisers, they should be applied immediately after Elidel.

Do not bath, shower or swim right after applying Elidel. This could wash off the cream.

How long to apply Elidel

Long term treatment should be intermittent and not continuous. Stop Elidel as soon as signs of eczema have disappeared.

Continue using the cream for as long as your doctor advises.

Stop the treatment and consult your doctor **if no improvement occurs after 6 weeks or if your eczema gets worse.**

In the long-term treatment of eczema, begin using Elidel as soon as you notice signs and symptoms (redness and itch). This helps to prevent progression to severe flare-ups.

If signs and symptoms return you should start treatment again.

If you apply more Elidel than you should

If you apply more cream to your skin than you needed to, just wipe it off.

If you forget to use Elidel

If you forget an application of the cream, apply it as soon as possible and then continue your normal dosing routine. However, if it is almost time for your next application, skip the missed dose and continue your normal dosing routine. Do not apply extra cream to make up for a missed dose.

If you accidentally swallow some Elidel

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

4. POSSIBLE SIDE EFFECTS

Like all medicines, Elidel cream can cause side effects, although not everybody gets 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

Rare side effects (affecting less than 1 in 1000 people)

- Allergic reactions which could cause swelling and pain, skin rashes or hives.

Very rare side-effects (affecting less than 1 in 10,000 people)

- Severe allergic reactions. Symptoms can include sudden wheezing, chest pain or tightening, and swelling of eyelids, face or lips.

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

Other side effects may include

Very common side effects (affecting more than 1 in 10 people)

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

Common side-effects (affecting more than 1 in 100 people)

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

Uncommon side effects (affecting less than 1 in every 100 people)

- 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 (affecting less than 1 in 1000 people)

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

Rarely, cases of cancer, including cancer of the lymph glands or skin, have been reported in patients using Elidel. However, a link to the treatment with Elidel cream has not been confirmed or refuted on the available evidence so far.

If any of the side effects gets severe, or if you notice any side effects not mentioned in this leaflet, **please tell your doctor or pharmacist.**

5. HOW TO STORE ELIDEL CREAM

Keep out of the reach and sight of children.

Do not store above 25°C. Do not freeze.

Store in the original package. Keep the tube tightly closed.

Do not use after the expiry date shown on the carton and tube.

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 carton.

6. FURTHER INFORMATION

What Elidel cream contains

- The active substance is pimecrolimus. 1 gram of Elidel cream contains 10mg of pimecrolimus.
- The other ingredients are: medium chain triglycerides, oleyl alcohol, propylene glycol, stearyl alcohol, cetyl alcohol, mono-and di-glycerides, sodium cetostearyl sulphate, benzyl alcohol, citric acid anhydrous, sodium hydroxide, purified water.

What Elidel looks like and contents of the pack

Elidel is a whitish, odourless, non-staining and easily spreadable cream. The cream is available in tubes of 5g, 15 g, 30 g, 60 g and 100 g. Not all pack sizes are necessarily available in your country.

Marketing Authorisation Holder

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Manufacturer

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If you have any questions or are unsure about anything regarding your medicine please ask your doctor or pharmacist.

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