

ELIDEL[®] CREAM

Pimecrolimus(10 mg/g)

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What Elidel Cream is used for

Elidel cream contains a medicine called pimecrolimus. It does not contain any steroids. Elidel cream is indicated for the short-term treatment and intermittent long term management of the signs and symptoms of mild to moderate atopic dermatitis (eczema) in individuals with normal immune system aged 2 years and older, in whom the use of alternative, conventional therapies is deemed inadvisable because of potential risks, or in the treatment of people who are not adequately responsive to or intolerant of alternative, conventional therapies.

How Elidel Cream works

It works in the cells in the skin that cause the inflammation and characteristic redness and itching of eczema. Pimecrolimus is an anti-inflammatory agent that can inhibit the production and releases of pro-inflammatory substance that help in reduce the inflammation and redness.

Before you use Elidel Cream

- When you must not take it

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

- Before you start to use it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

- **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.
- **Do not apply the cream to potentially malignant or pre-malignant skin lesions (cancer).**
- Elidel cream should not be applied to areas affected by bacteria and fungal infection until the infection has been adequately controlled.
- Elidel cream is not recommended in people with Netherton's syndrome or severely inflamed or damaged skin.
- **The use in people with impaired immune system is not recommended.**

- Taking 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.

You may need to stop using Elidel on the vaccination site after any **vaccinations.**

How to use Elidel Cream

- How much to use

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.

- When to use it

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

However, after a bath/shower, emollients should be applied before using Elidel cream.

- How long to use it

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 forget to use it

If you forget an application of the cream, apply it as soon as possible and then continue your normal dosing routine. However, if it 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 use too much (overdose)

If you apply more cream to your skin than you needed to, just wipe it off and/or rinsed with water

While you are using it

- Things you must do

If you have any further questions, ask your doctor or pharmacist. 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.

- Things you must not do

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

Do not apply Elidel to the breasts if breast-feeding.

- Things to be careful of

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.

Driving and using machines

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

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. Adverse reactions are ranked under heading of frequency, the most frequent first, using the following convention:

Very common ($\geq 1/10$); common ($\geq 1/100$, $< 1/10$); uncommon ($\geq 1/1,000$, $< 1/100$);

Rare ($\geq 1/10,000$, $< 1/1,000$); very rare ($< 10,000$), including isolated reports.

Skin and subcutaneous tissue disorders

Very common

Application site burning

Common

Application site reactions (irritation, itchiness and redness), skin infections (folliculitis)

Uncommon

Worsening of the condition, virus infection such as herpes simplex, skin inflammation (eczema herpeticum), rash, pain, dryness and swelling.

The following adverse reactions have been reported during post-marketing experience. The frequency has been estimated from the reporting rates. Because these reactions are reported voluntarily from a population of uncertain size, the frequency reflects only an estimate.

Rare

Allergic reactions (e.g. rash, hives, swelling) and skin discoloration

In most cases, flushing, rash, burning, itching or swelling occurred shortly after the intake of alcohol.

Rare cases of malignancy, including cutaneous and other types of lymphoma, and skin cancers, have been reported in people using pimecrolimus cream, although no causal relationship has been established

Immune system disorders

Very rare

Anaphylactic reactions which include generalized itching and hives, swelling, wheezing and difficulty breathing, fainting, and/or other allergy symptoms which may lead to death.

Metabolism and nutrition disorders

Rare

alcoholic intolerance

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.**

You may report any side effects or drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website portal.bpfk.gov.my (Consumers → Reporting)

Storage and Disposal of Elidel Cream

- Storage

- Keep out of the reach and sight of children.
- Do not store above 30°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.

- Disposal

Any unused product or waste material should be disposed of in accordance with local requirements.

Product description

What it looks like

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

Ingredients

- Active ingredient

The active substance is pimecrolimus.

- 1 gram of Elidel cream contains 10mg of pimecrolimus.

- Inactive ingredients

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.

- MAL number:

MAL20034628AZ

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