

LEAFLET: INFORMATION FOR THE USER

Elidel 10mg/g cream
pimecrolimus

Read the entire leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- Do you have any questions? Please contact your doctor or pharmacist.
- Do not pass this medicine on to others, as it has been prescribed for you only. It may harm them, even if their symptoms are the same as yours.
- Do you experience any side effects listed in section 4? Or do you experience a side effect not listed in this leaflet? Please contact your doctor or pharmacist.

In this leaflet:

1. What is Elidel cream and what is it used for?
2. When should you not use this medicine or be extra careful?
3. How to use this medicine?
4. Possible side effects
5. How to store this medicine?
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1. What is Elidel cream and what is it used for?

Elidel cream contains the medicine called pimecrolimus. It does not contain corticosteroids. This medicine specifically treats a skin inflammation 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 the signs and symptoms of mild to moderate eczema (e.g., redness and itching) in children (from 3 months to 17 years) and adults. When used to treat the early signs and symptoms, it can prevent progression to severe exacerbations/flare.

This medicine is only for use after other prescription medicines or emollients/skin care products have proven ineffective for you, or when your doctor has told you that you cannot use other medicines.

Contact your doctor if you do not feel better or if you feel worse after 6 weeks.

2. When should you not use this medicine or be extra careful with it?

Carefully follow all instructions given by your doctor. Read the following information before using this medicine.

When should you not use this medicine?

You are allergic to any of the ingredients in this medicine. You can find these ingredients in section 6.

When should you be extra careful with this medicine?

Discuss with your doctor before using this medicine if you have a weakened immune system (are immunocompromised), for any reason.

This medicine should only be used for eczema (atopic dermatitis). Do not use it for other skin conditions.

This medicine is intended for external use only. Do not use it in your nose, eyes, or mouth. If you accidentally apply it to these areas, the cream should be thoroughly wiped off and/or rinsed with water. Be careful not to swallow the cream or get it in your mouth if it is applied to your hands, for example.

Do not apply the cream to areas of the skin that are infected by a viral infection such as cold sores on/around the lips (herpes simplex) or chickenpox.

If your skin is infected, consult your doctor before using this medicine. If your skin is infected, your doctor may ask you to use an appropriate medicine to treat the infection. Once the infection at the treatment sites has cleared, treatment with this medicine can be started. If your skin becomes infected during treatment with this medicine, you should consult your doctor. Your doctor may then ask you to stop using this medicine until the infection is sufficiently under control.

This medicine may potentially lead to an increased risk of severe herpes simplex infection (eczema herpeticum). If you develop a painful rash with blisters anywhere, contact your doctor immediately. Stop treatment with this medicine until the infection has cleared.

This medicine may cause reactions at the application site such as a feeling of warmth or a burning sensation. These reactions are usually mild and transient. Inform your doctor immediately if you have a severe reaction to this medicine.

Do not cover the treated skin with plasters, bandages, or dressings during treatment with this medicine. However, you can wear normal clothing.

Avoid excessive exposure of the skin to sunlight, sunlamps, or tanning beds during treatment. If you go outside after applying this medicine, wear loose-fitting clothing that protects the treated areas from sunlight, use protective sunscreen products, and limit the time you spend in the sun.

If you have erythroderma (redness of almost the entire body) or a skin condition called Netherton syndrome, consult your doctor before starting to use this medicine.

Talk to your doctor before using this medicine if you have skin cancer (tumor). If your lymph nodes become swollen during treatment with this medicine, report this to your doctor.

Children

Use of Elidel is not recommended in patients younger than 3 months.

Are you using any other medicines?

Are you using any other medicines besides Elidel, or have you recently done so, or is there a possibility that you will use other medicines in the near future? Then tell your doctor or pharmacist.

Application of this medicine at a vaccination site, as long as the local reaction is present, is not recommended.

If you have extensive eczema, treatment with this medicine may need to be stopped before vaccination. Your doctor can tell you if this is necessary.

This medicine should not be used simultaneously with ultraviolet light treatments (such as UVA, PUVA, or UVB) or medicines that suppress the natural immune system (immunosuppressants) (such as azathioprine and ciclosporin).

Interactions with other medicines you are using are unlikely.

What should you pay attention to with food, drink, and alcohol?

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

Pregnancy and breastfeeding

If you are pregnant, breastfeeding, think you might be pregnant, or are planning to have a baby, ask your doctor or pharmacist for advice before using this medicine. You should not use this medicine if you are pregnant.

It is not known whether the active substance of this medicine passes into the milk after application to the skin. Do not apply this medicine to the breasts while breastfeeding.

Driving and using machines

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

Elidel cream contains cetyl alcohol and stearyl alcohol, which may cause local skin reactions (e.g., contact dermatitis). Elidel also contains 10 mg benzyl alcohol per gram of cream, which may cause allergic reactions and mild local irritation. Additionally, Elidel contains 50 mg propylene glycol (E1520) per gram of cream, which may cause skin irritation.

3. How to use this medicine?

Always use this medicine exactly as your doctor has told you. Are you unsure about the correct usage? Then contact your doctor or pharmacist.

You can use this medicine on all parts of the skin, including the head, face, and neck, and in the skin folds.

Apply the cream as follows:

Wash and dry your hands.

Open the tube. (Using the tube for the first time? Pierce the tube with the piercer in the cap).

Squeeze some cream from the tube onto your finger.

Apply a thin layer of this medicine. Cover the affected skin completely.

Apply the cream only to the areas of the skin affected by eczema.

Rub it in gently and completely.
Place the cap back on the tube.

The cream should be applied twice a day, for example, in the morning and evening. You can use moisturizing/care creams or lotions together with this medicine. If you use moisturizing/care creams or lotions, you can apply them immediately after this medicine.

Do not bathe, shower, or swim immediately after applying this medicine. The cream may wash off.

How long should you use this medicine

Long-term treatment should be intermittent and not continuous. Stop using this medicine as soon as the signs of eczema are gone.

Use this medicine for as long as your doctor has recommended.

If no improvement occurs after 6 weeks or if the eczema worsens, stop the treatment and consult your doctor.

In the long-term treatment of eczema, you should use this medicine from the moment the first symptoms (redness and itching) appear. This helps to prevent the disease from becoming severe. If the symptoms reappear, you should restart the treatment.

Have you used too much of this medicine?

If you have applied too much cream, wipe it off.

Did you forget to use this medicine?

If you accidentally forgot to apply the cream, apply it as soon as possible and continue with your normal schedule. However, if it is almost time for the next application, skip the missed dose and continue with the regular application schedule. Do not apply extra cream to make up for the missed dose.

If you stop using this medicine

Do you have any other questions about the use of this medicine? Then contact your doctor or pharmacist.

What to do if you accidentally swallowed some of this medicine

If you or someone else accidentally swallowed this medicine, contact your doctor immediately.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everyone gets them.

The most common side effects of this medicine are reactions (e.g., discomfort) at the application site. These reactions are usually mild to moderate in nature, occur at the beginning of treatment, and are short-lived.

Some side effects can be serious.

Rare side effects (occur in less than 1 in 1,000 users) are:

Angioedema, with symptoms such as itching, hives (urticaria), redness 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 (occur in less than 1 in 10,000 users) are:

Anaphylactic reaction: rash with red, itchy skin, swelling of the hands, feet, ankles, face, lips, mouth, and throat (these symptoms are described as angioedema and can cause difficulty swallowing and breathing) and you may feel faint.

If you experience any of these side effects shortly after using this medicine, stop using the cream and inform your doctor immediately.

Other side effects may include:

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

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

Common side effects (occur in less than 1 in 10 users):

Irritation, itching, and redness of the skin at the application site.
Skin infections (folliculitis).

Uncommon side effects (occur in less than 1 in 100 users):

Skin infections such as impetigo (caused by bacteria), cold sores (herpes simplex), shingles (herpes zoster), herpes simplex dermatitis (herpes infection on pre-existing skin lesions), skin-colored nodules (a viral skin infection - molluscum contagiosum), warts, and boils.

Reactions at the application site: rash, pain, tingling sensation, slight skin peeling, dryness and swelling, and worsening of eczema symptoms.

Rare side effects (occur in less than 1 in 1000 users):

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

Cases of malignant tumors, including lymphomas and skin cancer, have been reported in patients using this medication.

Cases of enlarged lymph nodes have been reported in patients using this medication. However, a connection with the use of this medication has not been established.

If any of these side effects worsen, or if you experience a side effect not listed in the leaflet, report it to your doctor or pharmacist.

Reporting side effects

If you experience side effects, contact your doctor, pharmacist, or nurse. This also applies to possible side effects not listed in this leaflet. You can also report side effects directly via the Netherlands Pharmacovigilance Centre Lareb Website: www.lareb.nl. By reporting side effects, you can help us obtain more information about the safety of this medicine.

5. How to store this medicine?

Keep out of the sight and reach of children.

Do not use this medicine after the expiry date. You can find it on the box and tube after “Do not use after”. It includes a month and a year. The last day of that month is the expiry date. Store below 25°C. Do not freeze.

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

Once opened, the tube must be used within 12 months. It may be helpful to write the date of first opening on the box.

Do not flush medicines down the sink or toilet and do not throw them in the trash. Ask your pharmacist what to do with medicines you no longer use. They will then be destroyed responsibly and will not enter the environment.

6. Contents of the packaging and other information

What substances are in this medicine?

The active substance in this medicine is pimecrolimus.

The other substances (excipients) in this medicine are triglycerides, oleyl alcohol, propylene glycol (E1520), stearyl alcohol, cetyl alcohol, mono- and diglycerides, sodium cetearyl sulfate, benzyl alcohol, citric acid (anhydrous), sodium hydroxide, and purified water.

This medicine contains 10 mg benzyl alcohol and 50 mg propylene glycol (E1520) per 1 gram of cream. See section 2.

What does Elidel cream look like and what is in a package?

Elidel cream is a whitish, odorless, non-staining, and easily spreadable cream. Elidel cream is available in tubes of 5, 15, 30, 60, and 100 grams.

Not all mentioned package sizes are marketed.

Marketing authorization holder and manufacturer

Marketing authorization holder Marketing authorization holder

Mylan Healthcare B.V. Krijgsman 20

1186 DM Amstelveen

Manufacturer

MEDA Manufacturing

Avenue J. F. Kennedy

33700 Merignac

France

Registered in the Register of Medicines under: RVG 28742

This medicine is registered in the member states of the EEA under the following names:

Belgium	Elidel 10 mg/g cream
Bulgaria	Елидел 10 mg/g крем
Cyprus	Elidel cream 10 mg/g
Denmark	Elidel 10 mg/g Creme
Germany	Elidel 10 mg/g Creme
Estonia	Elidel 10 mg/g kreem
Finland	Elidel 10 mg/g emulsiovoide
Greece	Elidel cream 10 mg/g
Hungary	Elidel 10 mg/g cream
Iceland	Elidel cream 10 mg/g
Italy	Elidel 10 mg/g cream
Croatia	Elidel 10 mg/g cream
Latvia	Elidel 10 mg/g cream
Lithuania	Elidel 10 mg/g cream
Luxembourg	Elidel 10 mg/g cream
Malta	Elidel 10 mg/g cream
Netherlands	Elidel 10 mg/g cream
Norway	Elidel 10 mg/g cream
Austria	Elidel 10 mg/g cream
Poland	Elidel 10 mg/g cream
Portugal	Elidel 10 mg/g cream
Romania	Elidel 10 mg/g cream
Slovakia	Elidel 10 mg/g cream
Slovenia	Elidel 10 mg/g cream
Spain	Elidel 10 mg/g cream
Czech Republic	Elidel 10 mg/g cream
Sweden	Elidel 10 mg/g cream
United Kingdom	Elidel 10 mg/g cream

If you have any questions or doubts about the use of this medicine, please consult your doctor or pharmacist.

This leaflet was last approved in January 2022.