297 mm
PAPIER : 45 g
148 mm
50 mm
1124
Sens de lecture
50 mm
1124
Sens de lecture
594 mm

- The other ingredients are: medium chain triglycerides, oleyl alcohol, propylene glycol (E 1520), stearyl alcohol, cetyl alcohol, mono-and di-glycerides, sodium cetostearyl sulphate, benzyl alcohol, citric acid anhydrous, sodium hydroxide, purified water.
- This medicine contains 10 mg benzyl alcohol and 50 mg propylene glycol (E 1520) in 1 g of cream. See section 2.

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 packsizes are necessarily available in your country.

Marketing Authorisation Holder
Viatris Products Limited,
Station Close,
Potters Bar,
EN6 1TL,
United Kingdom.

Manufacturer
MEDA Manufacturing,
Avenue J. F. Kennedy,
33700 Merignac,
France

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

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PACKAGE LEAFLET:
INFORMATION FOR THE USER

Elidel 10 mg/g cream

pimecrolimus

Read all of this 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.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:
1. What Elidel cream is and what it is used for
2. What you need to know before you use Elidel cream
3. How to use Elidel cream
4. Possible side effects
5. How to store Elidel cream
6. Contents of the pack and other information

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 3 months – 17 years 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.

You must talk to a doctor if you do not feel better or if you feel worse after 42 days.

2. What you need to know 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** to pimecrolimus or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions
Do not smoke or go near naked flames - risk of severe burns. Fabric (clothing, bedding, dressings etc) that has been in contact with this product burns more easily and is a serious fire hazard. Washing clothing and bedding may reduce product build-up but not totally remove it.

Speak to your doctor before using Elidel if you have a **weakened immune system** (immuno-compromised) whatever the cause.

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

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

Other medicines and Elidel cream
Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines.

Application of pimecrolimus to **vaccination sites**, as long as local reactions persist is not recommended.

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.

Elidel cream with food, drink and alcohol
In rare cases, you may experience flushing, rash, burning, itching or swelling shortly after drinking alcohol.

Pregnancy and breast-feeding
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking 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 breast-feeding.

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

Elidel contains cetyl alcohol and stearyl alcohol which may cause local skin reactions (e.g. contact dermatitis). Further Elidel also contains 10 mg benzyl alcohol per 1 g cream, which may cause allergic reactions and mild local irritation. Elidel also contains 50 mg propylene glycol (E 1520) per 1 g cream which may cause skin irritation.

3. How to use Elidel cream

Always use this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.
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 can 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 stop using Elidel cream
If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

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, this medicine 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)
- *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 (affecting less than 1 in 10,000 people)
- *anaphylactic reaction:* skin rash including red itchy skin, swelling of the hands, feet, ankles, face, lips, mouth or throat (these symptoms are also described as angioedema and may cause difficulty in swallowing or breathing) and you may feel you are going to faint.

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).

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 cream has not been established.

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.**

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Elidel cream

Keep out of the sight and reach of children.

Do not use this medicine after the expiry date shown on the carton and tube. The expiry date refers to the last day of that month.

Do not store above 25 °C. Do not freeze. Store in the original package.Keep the tube tightly closed.

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.

Do not throw away any medicines via wastewater. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Elidel cream contains
- The active substance is pimecrolimus. 1 gram of Elidel cream contains 10mg of pimecrolimus.