PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

Schedule 4

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM

Elidel ® 10 mg/g Cream

Pimecrolimus

Read all of this leaflet carefully before you start using Elidel ® 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.
- **Elidel®** has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their signs of illness are the same as yours.

1. WHAT Elidel® CONTAINS

Elidel® Cream contains a medicine called pimecrolimus. It does not contain any steroids.

The other ingredients are: propylene glycol, medium chain triglycerides, oleyl alcohol, stearyl alcohol, cetyl alcohol, mono-and di-glycerides, sodium cetostearyl sulphate, benzyl alcohol, citric acid anhydrous, sodium hydroxide and purified water.

2. WHAT Elidel® IS USED FOR

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.

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

3. BEFORE YOU USE Elidel®

Do not use Elidel® Cream:

- if you are **allergic** to pimecrolimus or any of the other ingredients of this medicine.

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.
- 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 2 years of age is not recommended until further data become available.

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® Cream contains cetyl alcohol and stearyl alcohol which may cause local skin reactions.

Elidel® also contains propylene glycol, which may cause skin irritation.

Other medicines and Elidel® Cream

Tell your doctor or pharmacist if you are taking, have recently taken or might take 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.

4. HOW TO USE Elidel®

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 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 use more Elidel® cream 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 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.

5. POSSIBLE SIDE EFFECTS

Like all medicines, **Elidel®** 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.**

Not all side effects reported for **Elidel®** are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking this medicine, please consult your doctor, pharmacist or other healthcare professional for advice.

6. STORING AND DISPOSING OF Elidel®

Store all medicines out of reach of children.

Store at or below 25 °C. Do not freeze.

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

Use within 12 months after first opening.

Do not use this cream after the expiry date shown on the carton or tube label.

If your cream becomes discoloured or shows any signs of deterioration, you should seek the advice of your pharmacist who will tell you what to do.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

7. PRESENTATION OF Elidel®

The cream is available in tubes of 30g and 60g (2x30g).

8. IDENTIFICATION OF Elidel®

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

9. REGISTRATION NUMBER

36/34/0522

10. NAME AND ADDRESS OF REGISTRATION HOLDER

Viatris South Africa (Pty) Ltd.

4 Brewery Street,

Isando, Johannesburg,

1609

11. DATE OF PUBLICATION

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