

אין לגרום להקאה ללא הוראה מפורשת מרופא!
תרופה זו נרשמה לטיפול במחלות, בחולה אחר/ת
היא עלולה להזיק. אל **תיתן/י תרופה זו** לקרויבך.
שכנוך או מכיר.

אין ליטול תרופות בחושך! יש לבדוק את התווים
והמנה **בכל פעם** שהינך מטל/ת תרופה. יש להריכב
משקפיים אם הנך איזוק/ה להם.

אחסנה:

לא להקפא. לאחסן מתחת ל- 25°C.
יש לשמרו באטיה הימורית. יש לשמר השפופרת
בקרטון. יש לשמר השפופרת סגורה.
מרגע שהשפופרת נפתחה, ניתן להשתמש בה תוך
12 שעות.

גם לפ' ואירוע האירוע/האחסנה הממליצים, תרופה
נשמרת לתקופה מוגבלת בלבד. נא שמש לב לתאריך
התפוגה של התכשוי בכל מקרה של ספק, לעיר
להוועץ ברוחך שספק לך את התרופה.
אין לאחסן תרופות שונות באותה אירוע.

מספר רישום התרופה: 00 30517 12 12 12

יצרן: מדיה מופקטורייג, מרינגן, צרפת עבו
מפה פארמה בע"מ, באד הומברוג, גרמניה.

בעל הרישום: מגאפרם בע"מ, ת.ד. 519

הו-השותן 4510501
פורמט עלון זה נקבע ע"י משרד הבריאות ותוכנו
נבדק ואושר בספטמבר 2009.

ELI PIL 092018 P2

PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) - 1986

The dispensing of this medicine
requires a doctor's prescription

**Read this package insert carefully
in its entirety before using this medicine**

Elidel® Cream 1% MEDA

Composition: Each 1 gram of cream contains:

Pimecrolimus 10 mg

Inactive ingredients: Triglycerides, oleyl alcohol, propylene glycol, stearyl alcohol, cetyl alcohol, mono- and di-glycerides, sodium cetostearyl sulphate, benzyl alcohol, citric acid, sodium hydroxide, purified water.

Therapeutic activity:

Elidel cream is a non-steroid medication that specifically treats inflammation of the skin and belongs to a class of medicines called topical calcineurin inhibitors. It works in the cells in the skin that cause the inflammation and the characteristic redness and itching of eczema.

Topical preparation indicated for the treatment of atopic dermatitis (eczema) in infants (3 months of age and above), children, adolescents and adults who did not respond to or could not be treated with topical corticosteroids.

When should the preparation not be used?

Do not apply Elidel to the breast if you are breastfeeding.
Do not use this medicine if you are sensitive to any of its ingredients.

Do not use this medicine without consulting a doctor before starting treatment:

If you are pregnant or think you may be pregnant. Inform the doctor if you become pregnant while using this medicine. If you are breastfeeding; it is not known whether the active ingredient in Elidel passes into the breast milk after application to the skin.

If you have any skin infection.

If you are suffering from impaired function of the immune system.

If you are suffering from Netherton's syndrome or from generalized erythroderma (inflammatory reddening of the entire skin).

Warnings:

Do not use this medicine for any purpose other than that for which it was prescribed.

Do not use this medicine continuously for a long time since the safety of using it for a prolonged period is not known.

In rare cases, patients have had cancer (e.g. skin or lymphoma) during treatment with topical calcineurin inhibitors, including Elidel. However, a causal link between the disease and the use of topical calcineurin inhibitors has not been shown.

Do not apply Elidel on potentially malignant skin lesions (check with your doctor if you are not sure).

Do not apply Elidel to areas of the skin affected by viral infection, e.g. herpes. In case of skin infection,

יש להעתמש בקרם באופן הבא:

1. שטוף/י ויבש/י את הידיים.

2. פתח/י את השפופרת (בפעמי הראשונה בה
תפתח/י את השפופרת, יש לפתח את החותם
תוך שימוש בבליטה שבקצת הפקק).

3. לחץ/י על השפופרת וחצאי קרם על אצבע.

4. מרוח/י שכבה דקה של קרם שאהזרו הנגע
יכוסה לחלוטין.

5. עשה/י את העור בעדרינות עד להחדרה מלאה של
הקרם.

6. סגור/י חזרה את השפופרת.

7. רוחץ/י את הידיים לאחר המריחה (אללא אם הן
מטפלות בקרם).

ניתן למרוח קרם לחות מיד לאחר השימוש בקרם
אליל, אבל, לאחר הרחצה, יש למרוח קרם לחות
לפני השימוש **באליל**.

כיצד תוכלי לסייע להצלחת הטיפול?

עליך להשלים את הטיפול שהומלץ על-ידי הרופא.

אם הוא שרג רופוי יש להפסיק את הטיפול.

משמעות הרעליה!

תרופה זו וכל תרופה אחרת שיישמר במיקום סגור
מחוץ להישגدم של ילדים/או תינוקות ועל-ידי כר
תמנע/י הרעללה. אם נטلت מנת יתר או אם בטעות
בלע וILD מון התרופה, פנה/י מיד לחדר מיון של
בית-חולים, ובaba/י או רשות הרווחה איזון.

refer to the attending doctor. The infection may need to be treated first.

Avoid exposing the skin to natural or artificial sunlight, including sun lamps, tanning beds or ultraviolet therapy. If you spend time outdoors after applying Elidel, use a sunscreen and wear loose fitting clothing that protects the skin from the sun. Limit sun exposure during treatment with Elidel even when the cream is not on your skin.

In addition, consult with your doctor regarding other appropriate sun protection measures.

The medicine contains ingredients (e.g. cetyl alcohol, propylene glycol, stearyl alcohol) that may cause local skin reactions or irritations.

Use of the medicine may cause mild temporary reactions (e.g. warmth or burning sensation), or skin irritation (e.g. itching and reddening) at the site of application. If such symptoms are severe notify your doctor.

Due to the alcohol content of the cream, application on wounds may cause irritation.

Drug interactions:

If you are taking another drug concomitantly or if you have just finished treatment with another medicine, inform the attending doctor, in order to prevent hazards or lack of efficacy arising from drug interactions.

If you have had a vaccination recently, do not apply Elidel to the site of the vaccination until the reddening and/or swelling disappear.

The medicine works selectively on the skin and a very small amount of the active ingredient is absorbed into the blood stream (where drug interactions occur). Therefore, the likelihood for drug interactions between this medicine and other medicines taken orally is low.

Side effects:

In addition to the desired effect of the medicine, adverse reactions may occur during the course of taking this medicine.

The most common side effects are a sensation of heat and/or burning at the application site.

Common side effects: Irritation, itching and reddening at the application site, inflammation of the skin such as folliculitis (inflammation of the hair follicles that may cause pustules).

Uncommon side effects: Worsening of the condition being treated, bacterial skin infections such as impetigo, viral skin infections such as herpes simplex, molluscum contagiosum, herpes simplex virus infected dermatitis (eczema herpeticum), rash, pain, feeling of prickling, slight scaling, dryness and swelling at the application site, warts, infection of the hair follicles and surrounding tissue (pustules).

These side effects usually are moderate, temporary, and appear at an early stage of treatment.

Additional side effects: Headache, cold or nasal congestion, sore throat, influenza, fever, viral infection and cough. Viral infections of the skin such as cold sores, chickenpox. Rarely, side effects such as facial flushing or skin irritations (e.g. rash, burning sensation, itching or swelling) may occur in patients who drink

Apply the cream as follows:

1. Wash and dry your hands.

2. Open the tube (when using the tube for the first time, open the seal by using the spike at the tip of the cap).

3. Squeeze the cream onto your finger.

4. Apply a thin layer of cream so that the affected area will be covered entirely.

5. Rub the cream in gently until it is completely absorbed.

6. Replace the cap on the tube.

7. Wash your hands after applying (unless they are the area being treated with the cream).

Moisturizers can be applied immediately after using Elidel. However, after bathing, moisturizers should be applied before using Elidel.

How can you contribute to the success of the treatment?

Complete the full course of treatment as instructed by the doctor. If the affected area is healed, treatment should be stopped.

Avoid poisoning! This medicine, and all other medicines, must be stored in a safe place out of the reach of children and/or infants, to avoid poisoning. If you have used an overdose, or if a child has accidentally swallowed the medicine, proceed immediately to a hospital emergency room and bring the package of the medicine with you. Do not induce vomiting unless explicitly instructed to do so by a doctor!

This medicine has been prescribed for the treatment of your ailment; in another patient it may cause harm.

Do not give this medicine to your relatives, neighbors or acquaintances.

Do not take medicines in the dark! Check the label and the dose each time you take your medicine.

Wear glasses if you need them.

Storage: Do not freeze. Store below 25°C.

Store in the original package, keep the tube in the outer carton, keep the tube tightly closed.

From the time the tube is opened, it should be used within 12 months. Even if kept in their original container and stored as recommended, medicines may be kept for a limited period only.

Please note the expiry date of the medicine! In case of doubt, consult the pharmacist who dispensed the medicine to you. Do not store different medications in the same package.

License number: 126 12 30517 00

Manufacturer: MEDA Manufacturing, Merignac, France for MEDA Pharma GmbH & Co. KG, Bad Homburg, Germany.

License Holder: Megapharm Ltd., P.O.B. 519, Hod Hasharon 4510501.

The format of this leaflet was determined by the Ministry of Health and its content was checked and approved in September 2009.

يجب إستعمال الكريم على الشكل التالي:

1- يجب غسل وتنشيف اليدين.

2- افتح/ي المسورة في البرة الأولى التي تفتح/ين بها المسورة، يجب فتح الختم باستعمال النوع البارز في طرف المقادير.

3- أخرج/ي الكريم إلى إصبعك بالضغط على المسورة.

4- إدهن/ي طبقة رقيقة من الكريم بحيث يغطي المنطقة المصابة بأكملها.

5- ذلك/ي الجلد بلطف حتى يتم التغلغل الكامل للكريم.

6- أغلق/ي المسورة ثانية.

7- إغسل/ي يديك بعد الدهن (إلا إذا كانت يداك هما المنطقة المعالجة بالكريم).

بالإمكان دهن الكريم مرطب حالاً بعد إستعمال الكريم. لكن،

بعد التغسيل، يجب دهن الكريم مرطب قبل إستعمال إليدل.

كيف تستطيع/ين أن تساهلي في نجاح العلاج؟

يجب إكمال العلاج الموصى به من قبل الطبيب.

إذا تم الشفاء، فيجب التوقف عن العلاج.

تجنب/ي للتسمم!

يجب حفظ هذا الدواء وكل دواء في مكان مغلق بعيداً عن متناول

أيدي الأطفال و/أو الرضع، وذلك لتفادي اصابةهم بالتسوس.

إذا أفرطت في استعمال المقادير الدوائية أو إذا بلع الطفل /ة خطأ

من هذا الدواء، عليك التوجه إلى المستشفى حالاً مصطحبًا

عبوة الدواء.

alcohol while under treatment with Elidel.

Rarely, a change in skin color (the skin becomes darker or lighter than the surrounding skin) may occur. In rare cases, patients have had cancer (e.g. skin or lymphoma) during treatment with Elidel. However, a causal relationship between the disease and treatment with Elidel has not been shown.

Side effects that require special attention:

On rare occasions, there may be an allergy to Elidel, which can cause swelling and pain, skin rash or hives. In very rare cases, the allergic reaction may be severe with symptoms such as sudden wheezing and chest pain or tightening, swelling of eyelids, face or lips.

If you experience any of these symptoms after using Elidel, stop treatment and contact your doctor immediately. Notify the attending doctor if your lymph nodes become swollen while using Elidel.

In the event that you experience side effects not mentioned in this leaflet, or if there is a change in your general health, consult your doctor immediately.

Recommended dosage unless otherwise prescribed by your doctor:

Apply the cream twice a day, in the morning and in the evening. When the signs and symptoms of atopic dermatitis (eczema) disappear, stop the treatment with Elidel. Start using Elidel again if the signs and symptoms reoccur. In long term treatment begin using Elidel as soon as you notice the signs and symptoms of eczema, in order to prevent progression of symptoms and severe flare-up of the disease.

If there is no improvement in the condition within 6 weeks, consult your doctor again. Sometimes, other skin diseases look like eczema.

If you forgot to apply the medicine at the specified time, apply a dose as soon as you remember and continue to apply at the regularly specified times.

If you accidentally applied a larger amount than necessary, wipe off the excess cream.

Attention:

Do not swallow! In the event that you swallowed the medicine, inform your attending doctor.

Elidel is intended for external use only.

Do not use it in your nose, eyes or mouth. If accidentally applied to these areas, wipe off the cream thoroughly, and rinse well with clean water. You should take care not to swallow the cream, or to accidentally transfer it into your mouth when for example it is applied to the hands.

Do not cover the treated area with an occlusive dressing.

Directions for use: