Cutivate Cream

PRESENTATION

Each gram of CUTIVATE Cream 0.05% contains 500 micrograms of fluticasone propionate.

List of excipients: Liquid Paraffin, Isopropyl Myristate, Cetosteraryl Alcohol, Macrogol Cetostesaryl Ether, Propylene Glycol, Imidurea, Disodium Phosphate Dodecahydrate, Citric Acid Monohydrate, Purified Water

INDICATIONS

Treatment of inflammatory dermatoses:

Adults:

Fluticasone propionate cream is a potent topical corticosteroid indicated for adults, children and infants aged 3 months and older for the relief of the inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses; these include the following:

- Atopic dermatitis (including infantile atopic dermatitis)
- Nummular dermatitis (discoid eczemas)
- Prurigo nodularis
- Psoriasis (excluding widespread plaque psoriasis)
- Lichen simplex chronicus (neurodermatitis) and lichen planus
- Seborrhoeic dermatitis
- Irritant or allergic contact dermatitis
- Discoid lupus erythematosus
- An adjunct to systemic steroid therapy in generalised erythroderma
- Insect bite reactions
- Miliaria (prickly heat)

Reduction of the risk of relapse:

Cutivate is indicated for the reduction of the risk of relapse of chronic recurrent atopic dermatitis, once an acute episode has been treated effectively.

DOSAGE AND ADMINISTRATION

Creams are especially appropriate for moist or weeping surfaces. **Adults, children and infants aged 3 months and over**

Treatment of inflammatory dermatoses:

Apply a thin layer and gently rub in using only enough to cover the entire affected area. Perform the treatment once or twice daily for up to 4 weeks until improvement occurs, then reduce the frequency of application or change the treatment to a less potent preparation. Allow adequate time for absorption after each application before applying an emollient. If the condition worsens or does not improve within 2-4 weeks, treatment and diagnosis should be re-evaluated.

Atopic dermatitis

Therapy with topical corticosteroids should be gradually discontinued once control is achieved and an emollient continued as maintenance therapy.

Rebound of pre-existing dermatoses can occur with abrupt discontinuation of topical steroids especially with potent preparations.

Reduction of the risk of relapse:

Once an acute episode has been treated effectively, application frequency should be reduced to once daily application, twice weekly, without occlusion. Application should be continued to all previously affected sites or to known sites of potential relapse. This regime should be combined with routine daily use of emollients. The condition must be re-evaluated on a regular basis.

Paediatric population

Children over 3 months

Children are more likely to develop local and systemic side effects of topical corticosteroids and, in general, require shorter courses and less potent agents than adults.

Safety and efficacy of the product for longer than 4 weeks in paediatric patients is not established.

Care should be taken when using fluticasone propionate to ensure the amount applied is the minimum that provides therapeutic benefit.

Elderly

Clinical studies have not identified differences in responses between the elderly and younger patients. The greater frequency of decreased hepatic or renal function in the elderly may delay elimination if systemic absorption occurs. Therefore the minimum quantity should be used for the shortest duration to achieve the desired clinical benefit.

Renal / Hepatic Impairment

In case of systemic absorption (when application is over a large surface area for a prolonged period) metabolism and elimination may be delayed therefore increasing the risk of systemic toxicity. Therefore the minimum quantity should be used for the shortest duration to achieve the desired clinical benefit.

CONTRAINDICATIONS

The following conditions should not be treated with fluticasone propionate:

Rosacea.

Acne vulgaris.

Perioral dermatitis.

Untreated cutaneous infections Perianal
and genital pruritus.

Pruritus without inflammation

Dermatoses in infants under three months, including dermatitis and nappy rash.

WARNINGS AND PRECAUTIONS

Fluticasone propionate should be used with caution in patients with a history of local hypersensitivity to corticosteroids or to any of the excipients in the preparation (see List of excipients). Local hypersensitivity reactions (see Adverse Reactions) may resemble symptoms of the condition under treatment.

Manifestations of hypercortisolism (Cushing's Syndrome) and reversible hypothalamicpituitary-adrenal (HPA) axis suppression, leading to glucocorticosteroid insufficiency, can occur in some individuals as a result of increased systemic absorption of topical steroids. If either of the above are observed, withdraw the drug gradually by reducing the frequency of application, or by

substituting a less potent corticosteroid. Abrupt withdrawal of treatment may result in glucocorticosteroid insufficiency (see Adverse Reactions). Risk factors for increased systemic effects are:

- Potency and formulation of topical steroid
- Duration of exposure
- Application to a large surface area
- Use on occluded areas of skin (e.g. on intertriginous areas or under occlusive dressings (in infants the nappy may act as an occlusive dressing)
- Increasing hydration of the stratum corneum
- Use on thin skin areas such as the face
- Use on broken skin or other conditions where the skin barrier may be impaired
- In comparison with adults, children and infants may absorb proportionally larger amounts of topical corticosteroids and thus be more susceptible to systemic adverse effects. This is because children have an immature skin barrier and a greater surface area to body weight ratio compared with adults.

Overt suppression of the HPA-axis (morning plasma cortisol less than 5 micrograms/dL) is very unlikely to result from therapeutic use of fluticasone propionate Cream unless treating more than 50% of an adult's body surface and applying more than 20 g per day.

Paediatric population

In infants and small children aged 3 months to 12 years of age, long-term continuous topical corticosteroid therapy should be avoided where possible, as adrenal suppression is more likely to occur.

Infection risk with occlusion

Bacterial infection is encouraged by the warm, moist conditions within skin folds or caused by occlusive dressings. When using occlusive dressings, the skin should be cleansed before a fresh dressing is applied.

Use in psoriasis

Topical steroids should be used with caution in psoriasis as rebound relapses, development of tolerance, risk of generalised pustular psoriasis and development of local or systemic toxicity due to impaired barrier function of the skin have been reported in some cases. If used in psoriasis, careful patient supervision is important.

Application to the face

Prolonged application to the face is undesirable as this area is more susceptible to atrophic changes.

Application to the eyelids

If applied to the eyelids, care is needed to ensure that the preparation does not enter the eye as cataract and glaucoma might result from repeated exposure.

Concomitant infection

Appropriate antimicrobial therapy should be used whenever treating inflammatory lesions which have become infected. Any spread of infection requires withdrawal of topical corticosteroid therapy and administration of appropriate antimicrobial therapy.

Chronic leg ulcers

Topical corticosteroids are sometimes used to treat the dermatitis around chronic leg ulcers. However, this use may be associated with a higher occurrence of local hypersensitivity reactions and an increased risk of local infection.

Visual disturbance

Visual disturbance may be reported with systemic and topical corticosteroid use. If a patient presents with symptoms such as blurred vision or other visual disturbances, the patient should be considered for referral to an ophthalmologist for evaluation of possible causes which may include cataract, glaucoma or rare diseases such as central serous chorioretinopathy (CSCR) which have been reported after use of systemic and topical corticosteroids.

CUTIVATE Cream contains the excipient propylene glycol as which may cause skin irritation. CUTIVATE Cream also contains cetostearyl alcohol and imidurea. Cetostearyl alcohol may cause local skin reactions (e.g. contact dermatitis). Imidurea releases formaldehyde as a breakdown product. Formaldehyde may cause allergic sensitisation or irritation upon contact with the skin.

INTERACTIONS

Co-administered drugs that can inhibit CYP3A4 (e.g. ritonavir, itraconazole) have been shown to inhibit the metabolism of corticosteroids leading to increased systemic exposure. The extent to which this interaction is clinically relevant depends on the dose and route of administration of the corticosteroids and the potency of the CYP3A4 inhibitor.

FERTILITY, PREGNANCY, LACTATION Fertility

There are no data in humans to evaluate the effect of topical corticosteroids on fertility.

Pregnancy

There are limited data from the use of fluticasone propionate in pregnant women.

Topical administration of corticosteroids to pregnant animals can cause abnormalities of foetal development. The relevance of this finding to humans has not been established. However, administration of fluticasone propionate during pregnancy should only be considered if the expected benefit to the mother is greater than any possible risk to the foetus. The minimum quantity should be used for the minimum duration.

Lactation

The safe use of topical corticosteroids during lactation has not been established. It is not known whether the topical administration of corticosteroids could result in sufficient systemic absorption to produce detectable amounts in breast milk. When measurable plasma levels were obtained in lactating laboratory rats following subcutaneous administration, there was evidence of fluticasone propionate in the milk. Administration of fluticasone propionate during lactation should only be considered if the expected benefit to the mother outweighs the risk to the infant.

If used during lactation, fluticasone propionate should not be applied to the breasts to avoid accidental ingestion by the infant.

EFFECT ON ABILITY TO DRIVE AND USE MACHINES

There have been no studies to investigate the effect of fluticasone propionate on driving performance or the ability to operate machinery. A detrimental effect on such activities would not be anticipated from the adverse reaction profile.

ADVERSE REACTIONS

Adverse events are listed below by organ class and frequency. Frequencies are defined as follows: very common (≥1/10), common (≥1/100 and <1/10), uncommon (≥1/1000 and <1/100), rare (≥1/10,000 and <1/1000) and very rare (<1/10,000) including isolated reports.

Infections and infestations

Very rare: Opportunistic infection.

Immune system disorders

Very rare: Hypersensitivity.

Endocrine disorders

Very rare: Hypothalamic-pituitary adrenal (HPA) axis suppression:

- Increased weight / obesity
- Delayed weight gain/growth retardation in children
- Cushingoid features (e.g. moon face, central obesity)
- Decreased endogenous cortisol levels
- Hyperglycaemia/glucosuria
- Hypertension
- Osteoporosis
- Cataract
- Glaucoma

Eye disorders

Not known: Vision, blurred (See Warnings and Precautions)

Skin and subcutaneous tissue disorders

Common: Pruritus

Uncommon: Local burning sensation

Very rare: Skin thinning, atrophy, striae, telangiectasias, pigmentation changes, hypertrichosis, allergic contact dermatitis, exacerbation of underlying symptoms, pustular psoriasis, erythema, rash, urticaria.

OVERDOSE

Symptoms and Signs

Topically applied fluticasone propionate may be absorbed in sufficient amounts to produce systemic effects. Acute overdosage is very unlikely to occur, however, in the case of chronic overdosage or misuse the features of hypercortisolism may appear (See Adverse Reactions).

Treatment

In the event of overdose, fluticasone propionate should be withdrawn gradually by reducing the frequency of application, or by substituting a less potent corticosteroid because of the risk of glucocorticosteroid insufficiency.

Given the risk of acute adrenal suppression, further management should be as clinically indicated.

STORAGE

Store as directed on the outer package. Do not freeze.

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Package leaflet: Information for the user

Cutivate Cream 0.05%w/w cream
Fluticasone propionate

Read all of this leaflet carefully before you start taking 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 Cutivate is and what it is used for

Cutivate Cream contains fluticasone propionate which belong to a group of medicines called steroids. Steroids help to reduce redness, swelling and irritation of the skin. Cutivate Cream relieves the symptoms of certain skin problems. These include:

- eczema
- prurigo nodularis (itchy nodules on the arms or legs)
- lichen simplex chronicus (patches of thickened, itchy skin, caused by scratching)
- lichen planus (a skin disease that causes itchy, reddish-purple, flat-topped bumps on the wrists, forearms or lower legs)
- seborrhoeic dermatitis (a red, scaly, itchy rash that develops on the face, scalp, chest and back)
- discoid lupus erythematosus (a disease of the skin most often affecting the face, ears and scalp causing scarring and increased sensitivity of the affected skin to sunlight).
- used in addition to oral or injectable steroids for erythroderma (inflammation, redness and scaling of the skin over most of the body)
- skin rash due to allergy or a substance that irritates your skin (irritant or allergic contact dermatitis)
- prickly heat
- insect bite reactions
- psoriasis (thickened patches of inflamed red skin, often covered by silvery scales)

For infants and children Cutivate Cream is used for dermatitis that has not responded to milder steroid creams or ointments.

2 What you need to know before using Cutivate

Don't use Cutivate Cream

- if you are allergic to fluticasone propionate or any of the other ingredients of this medicine (listed in section 6)
- for babies under three months
- to treat any of the following skin problems, it could make them worse:
    - infected skin (unless the infection is being treated with an anti-infective medicine at the same time)
    - acne
    - rosacea (a facial skin condition where the nose, cheeks, chin, forehead or entire face are unusually red)
    - rashes around the mouth
    - itchy skin which is not inflamed around the anus or genitals (penis and vagina)

➔ If you think any of these apply to you, **don't use** Cutivate Cream until you have checked with your doctor or pharmacist.

Take special care with Cutivate Cream

- Only use Cutivate Cream for as long as your doctor recommends. If your condition does not improve after 2-4 weeks of treatment, speak to your doctor.
- If you experience blurred vision or other visual disturbances, speak to your doctor.
- Take care when applying Cutivate Cream to the eyelids to make sure it does not get into your eye.
- Take care when applying Cutivate Cream to the face over a long period of time as it may cause skin thinning.
- If you have eczema around a leg ulcer use of a topical corticosteroid may increase the risk of an allergic reaction or an infection around the ulcer.
- Only use an airtight dressing over this medicine if your doctor has told you to. If you are applying Cutivate Cream under an airtight dressing, including a child's nappy, make sure that the skin is cleaned before a fresh dressing is applied to prevent infections.

➔ Contact your doctor if an infection develops. *(See Section 4 Possible Side Effects)*

Other medicines and Cutivate Cream

Some medicines may affect how Cutivate Cream works, or make it more likely that you'll have side effects. Examples of these medicines include:

- Ritonavir and itraconazole

➔ **Tell your doctor or pharmacist** if you are taking any of these.

There are other medicines which may have a similar effect. It's therefore very important to **tell your doctor or pharmacist** if you're taking any other medicines, if you've taken any recently, or if you start taking a new one. This includes medicines bought without a prescription.

Pregnancy and breast-feeding

If you are **pregnant**, or **think you could be**, or if you are **planning to become pregnant**, **don't use** Cutivate Cream without talking to your doctor first.

If you are breast-feeding, you must check with your doctor before you use Cutivate Cream.

If you do use Cutivate Cream when breast-feeding, don't use Cutivate Cream on your breast area to ensure that the baby does not accidentally get Cutivate Cream in their mouth.

Cutivate Cream contains the ingredient imidurea. Your body can break down imidurea into small amounts of a chemical called formaldehyde. This chemical may cause a skin reaction including redness and itchiness.

3 How to use Cutivate

Always use Cutivate Cream exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

How much to use
Use Cutivate Cream once or twice a day. The number of times you use your medicine may be reduced as your skin gets better or your doctor may prescribe a weaker steroid for you to use instead.

How to use

- Apply a thin layer and gently rub in, using only enough to cover the entire affected area.
- Wash your hands after use unless treating the hands.
- If you are also using an emollient (moisturising) preparation allow time for Cutivate Cream to be absorbed after each application before applying the emollient.
- This medicine should not be used every day for more than four weeks

If your eczema flares up frequently your doctor may suggest that you use a less frequent dose of Cutivate Cream once your eczema is under control, to help stop your eczema from coming back.
For example, your doctor may advise you to apply a thin film of Cutivate Cream once daily, two times a week to areas of skin which have been affected by eczema, or to those areas where it is likely to re-appear.

If you forget to use Cutivate Cream

- If you forget to use Cutivate Cream apply it as soon as you remember then continue as before.
- Don't apply extra Cutivate Cream to make up for missed doses.

Don't stop using Cutivate Cream without advice

If you use Cutivate Cream regularly make sure you talk to your doctor before you stop using it.

If you use too much Cutivate Cream
If you apply a large amount of Cutivate Cream or accidentally swallow a lot of Cutivate Cream, it could make you ill. If you do swallow a large amount of Cutivate Cream, rinse your mouth out with plenty of water and contact your doctor or pharmacist for advice. ➔ **Ask your doctor or pharmacist for advice.**

4 Possible side effects

Like all medicines Cutivate Cream can have side effects although not everybody gets them. Side effects will affect your skin and may affect other parts of your body if a sufficient quantity of medicine is absorbed through the skin and enters your blood stream.

If your skin condition gets worse or your skin becomes swollen during treatment. You may be allergic to the medicine, have an infection or need other treatment.

➔ **Stop using Cutivate Cream and tell your doctor as soon as possible.**

Common side effects

These may affect up to **1 in 10 people.**

- Itching

Uncommon side effects

These may affect up to **1 in 100 people**.

- Local skin burning

Very rare side effects

These may affect up to **1 in 10,000 people**.

Use of Cutivate Cream for a long period of time, or use under an airtight dressing, may cause the following symptoms:

- increased weight
- moon face / rounding of the face
- obesity
- skin thinning, this may cause stretch marks
- the appearance of blood vessels under the surface of your skin
- changes to the colour of your skin
- increased body hair

Other very rare skin reactions that may occur are:

- allergic reaction at the site of application
- worsening of condition
- redness
- rash or hives
- If you have psoriasis you may get raised bumps with pus under the skin. This can happen very rarely during or after treatment and is known as pustular psoriasis - skin infection

In children also look out for the following symptoms:

- delayed weight gain
- slow growth

Very rare side effects that may show up in blood tests or when your doctor gives you a medical examination:

- a decrease in the level of the hormone cortisol in your blood
- increased levels of sugar in your blood or urine
- high blood pressure
- cloudy lens in the eye (cataract)
- increased pressure in the eye (glaucoma)
- weakening of the bones through gradual loss of mineral (osteoporosis). Additional tests may be needed after your medical examination to confirm if you have this condition.

If you get side effects

➔ **Tell your doctor or pharmacist** if any of the side effects listed becomes **severe or troublesome**, or if you notice any side effects not listed in this leaflet.

5 How to store Cutivate

Keep out of the reach and sight of children. It may harm them.

Don’t use after the expiry date shown as "Exp" on the carton and label.

Store as directed on the outer package. Do not freeze.

6 Contents of the pack and other information

The active ingredient is fluticasone propionate. Each 1 g contains 0.5mg of fluticasone propionate (0.05%w/w).

The other ingredients of the cream are: Liquid Paraffin, Isopropyl Myristate, Cetosteraryl Alcohol, Macrogol Cetostesaryl Ether, Propylene Glycol, Imidurea, Disodium Phosphate Dodecahydrate, Citric Acid Monohydrate, Purified Water.
Version: HK072018(GDS14)

包裝單張：使用者須知

克廷膚乳膏（**0.05%w/w** 乳膏）
Fluticasone propionate

用藥前請仔細閱讀本說明書，因為其中包含重要資訊。

- 請保留本單張。您可能需要再次閱讀。
- 如果您有任何進一步的疑問，請向您的醫生或藥劑師諮詢。
- 請勿擅自將本藥物傳給他人。儘管他人的症狀和您一樣，但是還是可能會對他們造成傷害。
- 如果您出現了任何副作用，請諮詢您的醫生或藥劑師。這包括未在本單張中列出的任何可能的副作用。請參閱第 4 部分。

本說明書所含內容：

1. 克廷膚（Cutivate）是甚麼及有何用途

克廷膚（Cutivate）含有一種名為 fluticasone propionate 的藥物，屬於類固醇類藥物，有助減輕皮膚泛紅、痕癢和刺激。它能夠減輕某些皮膚問題的症狀。
這包括：

- 濕疹
- 結節性癢疹（prurigo nodularis）（一種皮膚病，四肢出現痕癢結節）
- 慢性單純性苔癬（抓刮所致的皮膚增厚、痕癢）
- 扁平苔蘚（lichen planus）（一種皮膚病，會造成手腕、小臂或小腿部位出現痕癢、紫紅色、扁平的腫塊）脂溢性皮炎（紅色、鱗片狀、痕癢皮疹，發生於面部、頭皮、胸部和背部）。
- 盤狀紅斑狼瘡（discoid lupus erythematosus）（一種皮膚病，最常影響到面部、耳部和頭皮，產生疤痕並讓患病皮膚對陽光格外敏感）
- 正在服用或注射類固醇以治療紅皮病（身體大部分皮膚發炎、泛紅和脫屑）
- 因皮膚過敏或受到物質刺激所導致的紅疹（刺激性或接觸性皮膚炎）
- 熱痱 (prickly heat)
- 蚊蟲叮咬反應
- 銀屑病（psoriasis）（皮膚變厚並且發炎及變得紅腫，通常被銀白色鱗屑所覆蓋）

對於嬰幼兒和兒童，克廷膚（Cutivate）乳膏可用於治療，對藥效較溫和的類固醇乳膏/油膏有耐受性的皮炎。

2. 在使用克廷膚（Cutivate）前，您需要了解哪些資訊

如有以下情況，切勿使用克廷膚（Cutivate）

- 如果您對 fluticasone propionate 或本藥物中的任何其他成份有嚴重過敏反應（在第 6 部分 包裝內容和其他資訊中列出）
- 三個月以下的嬰兒
- 用於治療以下任何皮膚問題，本藥可能會加重病情：
    - 皮膚感染（除非同時在使用抗感染藥物治療感染）
    - 暗瘡
    - 鼻子以及鼻子周圍區域出現的嚴重潮紅（玫瑰痤瘡（rosacea））
    - 嘴部周圍點狀紅色皮疹
    - 肛門和生殖器（陰莖或陰道）周圍痕癢

➔ 如果任何上述情況適用於您，在諮詢醫生或藥劑師前，切勿使用本藥。

警告和注意事項

- 必須接照醫生指示用藥。如果您的情在用藥 2-4 週後未見好轉，請諮詢醫生。
- 如出現視力模糊或其他視覺障礙，請告知你的醫生。
- 在眼瞼部位用藥時必須小心，以確保藥膏不會進入眼中。
- 在面部長期用藥時必須注意，因為這可能導致皮膚變薄。
- 如果濕疹位於腿部潰瘍周圍，外用類固醇可能會增加過敏反應或感染的風險。
- 只有在醫生建議的情況下，才可在不透氣的敷料下使用乳膏。如果在不透氣的敷料下面使用本藥，包括嬰幼兒尿布，應確保在換上新敷料前清潔皮膚，以防止感染。

➔ 如果在使用本藥物的過程中出現感染，請聯絡您的醫生。（請參閱第 4 部分可能出現的副作用）

其他藥物與克廷膚（Cutivate）

某些藥物可影響克廷膚（Cutivate）的藥效或增加其產生副作用的風險。這些藥物包括：

- Ritonavir 和 itraconazole

➔ 如果您正在服用這些藥物，請告知醫生或藥劑師。

其他藥物也可能有類似影響。因此，如果您最近正在服用，或近期服用過，或可能開始使用新藥，必須告訴醫生或藥劑師。這包括您購買的非處方藥。

懷孕和哺乳

如果您已經懷孕、認為自己可能懷孕、或正在計劃懷孕，在諮詢醫生前切勿使用本藥。

如果您正在哺乳期，在使用本藥前必須諮詢醫生。

如果您在哺乳期的確要使用克廷膚（Cutivate），切勿將本藥物用於乳房周圍，避免嬰兒誤將本藥物食入口中。

克廷膚（Cutivate）乳膏中含有 imidurea。人體可將 imidurea 分解為化學物質甲醛。這種化學物質可導致皮膚泛紅和痕癢。

3 如何使用 Cutivate（克廷膚）乳膏

請始終嚴格按照醫生指示用藥。如果您有不明白的地方，請與您的醫生或藥劑師確認。

用量
每日 1 - 2 次。隨著皮膚情況有所好轉，可減少用藥次數，或由醫生更換藥效更溫和的類固醇。

如何使用
- 將少量克廷膚（Cutivate）薄薄地塗於患處，輕揉直至藥物被皮膚吸收，只須使用僅足以覆蓋整個患處的用量。
- 除非您要將本藥物塗於自己手上作為治療的一部分，否則用後請洗手。
- 如果您還在使用潤膚劑（保濕乳霜），請先等待克廷膚（Cutivate）被皮膚充分吸收後再使用潤膚劑。
- 不應連續用藥超過 4 週。

如果濕疹經常發作，在病情得到有效控制後，醫生可能會建議減少克廷膚（Cutivate）的使用次數，以防止濕疹復發。
例如：醫生可能建議您在患處或可能復發的部位薄薄地塗上乳膏，劑量為每日 1 次或每週 2 次。

如果您忘記使用克廷膚（Cutivate）
- 如果忘記用藥，應在記起時立即使用，然後繼續照常用藥。
- 請勿因為忘記用藥而一次性使用較大劑量。

切勿在沒有醫生指示的情況下擅自停用克廷膚（Cutivate）

如果您經常使用本藥，在停用前，必須告知您的醫生。

如果您使用了過量的克廷膚（Cutivate）
如果您使用了過量的克廷膚（Cutivate），或不小心吞服本藥物，您可能會因此產生不適。請用大量清水漱口並諮詢您的醫生或藥劑師。
➔ 諮詢您的醫生或藥劑師。

4 可能出現的副作用

和所有藥物一樣，本藥物也會引發一些副作用，儘管並非所有人都會出現這些症狀。
副作用會影響您的皮膚，如果大量的藥物經由皮膚吸收進入血液，可能會影響身體的其他部位。

如果在用藥期間，皮膚問題惡化或皮膚出現腫脹，則表示您可能對本藥過敏、出現感染或需要接受其他治療方法。
➔ 停止用藥並盡快告知您的醫生。

常見（每 10 名患者中最多有 1 人會受影響）

- 痕癢

不常見（每 100 名患者中最多有 1 人會受影響）
- 皮膚局部感到灼燒

極為罕見（每 10,000 名患者中最多有 1 人會受影響）
長期使用克廷膚（Cutivate）或在不透氣敷料遮蓋的情況下使用可導致以下症狀：
- 體重增加
- 滿月臉/面部變圓
- 肥胖
- 皮膚變薄，這可能導致皮膚起皺
- 皮下血管會變得更加清晰可見
- 膚色改變
- 體毛增多

其他可能發生的、極為罕見的皮膚反應包括：
- 用藥處出現過敏反應
- 病情惡化
- 發紅
- 皮疹或風疹
- 如果患有銀屑病（psoriasis），您可能會在皮下出現凸起的化膿腫塊。這是治療當中或

治療結束之後可能出現的極為罕見的情況，它被稱為膿皰性銀屑病（pustular psoriasis）
- 皮膚感染

對於兒童，也要注意以下症狀：
- 體重增加推遲
- 生長發育遲緩

在血液測試中或在醫生進行的檢查中，可能發現的極為罕見的副作用：
- 血液中皮質醇水平下降
- 血液或尿糖水平升高
- 高血壓
- 晶狀體渾濁（白內障）
- 眼壓增高（青光眼）
- 礦物質逐漸流失導致骨骼變得脆弱（骨質疏鬆症 osteporosis）。在檢查身體後，可能需要接受額外測試以確認您是否存在這一情況。

如果出現了副作用
➔ 如果上述副作用較嚴重或令您感到困擾，又或發現本單張中未列出的副作用，應告知您的醫生或藥劑師。

5 如何存放克廷膚（Cutivate）

請將本藥物放在兒童無法看見並觸及的地方。本藥可能對兒童造成傷害。
如果克廷膚（Cutivate）放置超過了藥膏管和包裝盒上印制的有效期，切勿使用。

請根據外包裝指示存放。
不可冷凍。

6 包裝內容和其他資訊

本藥的活性成分為 fluticasone propionate。每 1 克乳膏含 0.5 毫克 fluticasone propionate(0.05%w/w)。其他成分包括：Liquid Paraffin, Isopropyl Myristate, Cetosteraryl Alcohol, Macrogol Cetostesaryl Ether, Propylene Glycol, Imidurea, Disodium Phosphate Dodecahydrate, Citric Acid Monohydrate, Purified Water

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