EUMOVATE CREAM

Presentation

Eumovate Cream contains 0.05% w/w clobetasone butyrate, and is white in appearance. The emollient cream is water miscible.
Excipients: Glycerol, Glycerol monostearate, Cetostearyl alcohol, Beeswax substitute 6621, Arlacel 165, Dimeticone 20, Chlorocresol, Sodium citrate, Citric acid monohydrate, Purified water. This product contains paraffin (*see section Special Warnings and Precautions for Use*).

Indications

Eumovate Cream is a moderately potent topical corticosteroid indicated for adults, elderly, children and infants for the relief of the inflammatory and pruritic manifestations of steroid responsive dermatoses.

These include the following:

- Atopic dermatitis

- Irritant or allergic contact dermatitis

- Seborrhoeic dermatitis

- Nappy rash

- Photodermatitis

- Otitis externa

- Prurigo nodularis

- Insect bite reactions

Eumovate may be used as maintenance therapy between courses of one of the more potent topical steroids.

Dosage and Administration

Route of administration: Cutaneous

Adults, Elderly, Children and Infants

Creams are especially appropriate for moist or weeping surfaces.

Apply thinly and gently rub in using only enough to cover the entire affected area once or twice a day 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.

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 corticosteroids especially with potent preparations.

Duration of treatment for adults and elderly

Continuous daily treatment for longer than four weeks is not recommended. If the condition worsens or does not improve within four weeks, treatment and diagnosis should be re-evaluated.

Paediatric population

Use in children under 12 years should be on the advice of a doctor.

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

Duration of treatment for children and infants

When clobetasone is used in the treatment of dermatoses in children, extreme caution is required and treatment should not normally exceed 7 days.

If the condition worsens or does not improve within 7 days, treatment should be reviewed. Once the condition has been controlled, the frequency of application should be reduced to the lowest effective dose for the shortest possible time.

Continuous daily treatment for longer than 4 weeks is not recommended.

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

Hypersensitivity to the active substance or any of the excipients listed.

The following conditions should not be treated with Eumovate:

• Untreated cutaneous infections.

• Rosacea

• Acne vulgaris

• Pruritus without inflammation.

Special Warnings and Precautions for Use

Eumovate should be used with caution in patients with a history of local hypersensitivity to **other** corticosteroids. Local hypersensitivity reactions (*see section Undesirable effects*) may resemble symptoms of the condition under treatment.

Manifestations of hypercortisolism (Cushing's syndrome) and reversible hypothalamic-pituitary-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 (s*ee section Undesirable effects).*

Risk factors for increased systemic effects are:

o Potency and formulation of topical steroid

o Duration of exposure

o Application to a large surface area

o Use on occluded areas of skin e.g. on intertriginous areas or under occlusive dressings (in infants the nappy can be considered as an occlusive dressing).

o Increasing hydration of the stratum corneum

o Use on thin skin areas such as the face

o Use on broken skin or other conditions where the skin barrier may be impaired

o In comparison with adults, children and infants may absorb proportionally larger amounts of topical corticosteroids and thus be more susceptible to systemic adverse effects.

Paediatric population

Children are more likely to develop local and systemic adverse reactions due to the use of local corticosteroids because of their higher surface area to body mass ratio and, in general, require a shorter treatment.

Particularly, in infants and toddlers the nappy can be considered as an occlusive dressing and therefore can enhance absorption.

In infants and children under 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.

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.

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.

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.

Accidental ingestion

For external use only. This and all medication should be kept out of the reach of children. In case of accidental ingestion, professional assistance should be sought immediately (se*e section Overdose*).

Eumovate Cream contains cetostearyl alcohol which may cause local skin reactions (e.g. contact dermatitis) and chlorocresol which may cause allergic reactions.

Flammability risk

Product contains paraffin. Instruct patients not to smoke or go near naked flames due to the 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.

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 and 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 clobetasone in pregnant women.

Topical administration of corticosteroids to pregnant animals can cause abnormalities of foetal development. *(see section Preclinical safety data)*

The relevance of this finding to humans has not been established. Administration of clobetasone during pregnancy should only be considered if the expected benefit to the mother outweighs the 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.

Administration of clobetasone during lactation should only be considered if the expected benefit to the mother outweighs the risk to the infant.

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

Effects on ability to drive and use machines

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

Undesirable Effects

Adverse drug reactions (ADRs) are listed below by MedDRA system organ class and by frequency. Frequencies are defined as: very common (≥1/10), common (≥1/100 and <1/10), uncommon (≥1/1,000 and <1/100), rare (≥1/10,000 and <1/1,000) and very rare (<1/10,000), including isolated reports.

Post-marketing data

Infections and Infestations

Very rare	Opportunistic infection

Immune System Disorders

Very rare	Hypersensitivity, generalised rash

Endocrine Disorders

Very rare	Hypothalamic-pituitary adrenal (HPA) axis suppression: Cushingoid features (e.g. moon face, central obesity), delayed weight gain/growth retardation in children, osteoporosis, glaucoma, hyperglycaemia/glucosuria, cataract, hypertension, increased weight/obesity, decreased endogenous cortisol levels

Skin and Subcutaneous Tissue Disorders

Very rare	Allergic contact dermatitis, urticaria, skin atrophy*, pigmentation changes*, exacerbation of underlying symptoms, local skin burning, hypertrichosis, rash, pruritus, erythema

Skin features secondary to local and/or systemic effects of hypothalamic- pituitary adrenal (HPA) axis suppression.*

Eye disorders

Not known	Vision, blurred (see also section *Special Warnings and Precautions for Use*)

Overdose

Symptoms and signs

Topically applied clobetasone 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 occur (s*ee section Undesirable Effects*).

Treatment

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

Further management should be as clinically indicated.

Pharmacological properties

Pharmacodynamic properties

ATC code

D07AB Corticosteroids, moderately potent (group II)

Mechanism of action

Topical corticosteroids act as anti-inflammatory agents via multiple mechanisms to inhibit late phase allergic reactions including decreasing the density of mast cells, decreasing chemotaxis and activation of eosinophils, decreasing cytokine production by

lymphocytes, monocytes, mast cells and eosinophils, and inhibiting the metabolism of arachidonic acid.

Pharmacodynamic effects

Topical corticosteroids, have anti-inflammatory, antipruritic and vasoconstrictive properties.

Clobetasone butyrate has little effect on hypothalamo-pituitary-adrenal function. This was so even when Eumovate was applied to adults in large amounts under whole body occlusion.

Clobetasone butyrate is less potent than other available corticosteroid preparations and has been shown not to suppress the hypothalamo-pituitary-adrenal axis in patients treated for psoriasis or eczema.

Pharmacological studies in man and animals have shown that clobetasone butyrate has a relatively high level of topical activity accompanied by a low level of systemic activity.

Pharmacokinetic properties

Absorption and Distribution

Topical corticosteroids can be systemically absorbed from intact healthy skin. The extent of percutaneous absorption of topical corticosteroids is determined by many factors, including the vehicle and the integrity of the epidermal barrier. Occlusion, inflammation and/or other disease processes in the skin may also increase percutaneous absorption.

A single application of 30g clobetasone butyrate 0.05% ointment to eight patients resulted in a measurable rise in plasma clobetasone butyrate levels during the first three hours but then the levels gradually decreased. The maximum plasma level reached in the first three hours was 0.6ng/ml. This rise in levels was followed by a more gradual decline with plasma levels of clobetasone butyrate falling below 0.1ng/ml (the lower limit of the assay) after 72 hours. The normal diurnal variation in plasma cortisol levels was not affected by the application of clobetasone butyrate ointment

The use of pharmacodynamic endpoints for assessing the systemic exposure of topical corticosteroids is necessary due to the fact that circulating levels are well below the level of detection.

Metabolism

Once absorbed through the skin, topical corticosteroids are handled through pharmacokinetic pathways similar to systemically administered corticosteroids. They are metabolised, primarily in the liver.

Elimination

Topical corticosteroids are excreted by the kidneys. In addition, some corticosteroids

and their metabolites are also excreted in the bile.

Preclinical safety data

Genotoxicity and Carcinogenesis

Conventional i*n vitro* and *in vivo* genotoxicity studies reveal no hazard for humans.

Long-term animal studies have not been performed to evaluate the carcinogenic potential of topical clobetasone.

Reproductive toxicity

Topical application of clobetasone to rats at doses of 0.5 or 5 mg/kg/day, and subcutaneous administration to mice at doses ≥3 mg/kg/day or rabbits at doses ≥30 µg/kg/day during pregnancy resulted in foetal abnormalities including cleft palate, intrauterine growth retardation and foetal loss.

Incompatibilities

None known

Shelf-life

The expiry date is indicated on the packaging.

Storage

Please refer to the outer packaging

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Package Leaflet: Information for the User

Eumovate Cream
clobetasone butyrate

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 Eumovate is and what it is used for

Eumovate contains a medicine called clobetasone butyrate. It belongs to a group of medicines called steroids that reduce swelling and irritation.
Eumovate is used to

- help reduce the redness and itchiness of certain skin problems. It is used for mild skin problems or to keep your skin problem under control. These skin problems include eczema, dermatitis, nappy rash or insect bites.
- help reduce inflammation of the outer ear.

2. What you need to know before you use Eumovate

Do not use Eumovate:

- if you are allergic to clobetasone butyrate or any of the other ingredients of this medicine (listed in section 6)
- 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
  - severe flushing of skin on and around your nose (rosacea)
  - itchy skin which is not inflamed

Do not use if any of the above apply to you. If you are not sure, talk to your doctor or

pharmacist before using Eumovate.

Warning and precautions

Talk to your doctor or pharmacist before using Eumovate if:

- you have previously had an allergic reaction with another steroid
- using around a chronic leg ulcer as you may be at increased risk of local allergic reaction or infection
- you have been advised by your doctor to use this medicine under an occlusive dressing (including a child's nappy). Make sure that the skin is cleansed before a fresh dressing is applied to prevent infections. Occlusive dressings (including a child's nappy) make it easier for the active ingredient to pass through the skin, making it possible to accidentally use too much.
- you are applying to thin skin such as the face, as skin is thinner and may absorb larger amounts. Dressings or bandages should not be used on the face where the cream is applied.
- you are applying to the face over a long period of time as it may cause skin thinning.
- you are applying the cream on broken skin or within the skin folds.
- you are applying near eyes or on eyelids, as cataracts or glaucoma may result if the cream repeatedly enters the eye.
- you accidentally swallow a large amount of Eumovate, rinse the mouth out with plenty of water and contact a doctor or pharmacist for advice **immediately**.
- if an infection develops (see section 4, Possible side effects)

Contact your doctor if you experience blurred vision or other visual disturbances.

Children

- Treatment in children under 12 years of age should not normally exceed 7 days.
- Prolonged daily treatment in children can affect their growth. Continuous daily treatment for longer than 4 weeks is not recommended.

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before using this medicine.

Other medicines and Eumovate

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicine, especially if you are taking ritonavir and itraconazole medications.

Pregnancy, breast-feeding and fertility

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.

Eumovate Cream contains chlorocresol and cetostearyl alcohol

Eumovate cream contains chlorocresol which may cause allergic reactions and cetostearyl alcohol which may cause local skin reactions (e.g. contact dermatitis).

Whilst using Eumovate do not smoke or go near naked flames due to the risk of severe burns. Fabric (clothing, bedding, dressing 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.

3. How to use Eumovate

Always use this medicine exactly as your doctor has told you. Check with your doctor or

pharmacist if you are not sure.

Using this medicine

- You usually apply Eumovate up to 2 times a day. This may be reduced as your skin begins to get better.
- This cream is for use on your skin only.
- Do not use on large areas of the body for a long time (such as every day for many weeks or months) - unless your doctor tells you to.
- If you are using an emollient (moisturising) preparation allow time for Eumovate to be absorbed after each application before applying the emollient.
- If you are applying the cream on someone else make sure you wash your hands after use or wear disposable plastic gloves.
- If your skin problem does not improve after 4 weeks, talk to your doctor.

Guidance on how to apply the cream

1. Wash your hands.
2. Apply a thin layer to the affected area(s) and gently rub into the skin until it has all disappeared. You can measure how much Eumovate to use with your fingertip. For children you will need to use less cream but still use an adult finger to measure out the fingertip unit. This picture shows one fingertip unit.

3. Unless you are meant to apply the cream to your hands as a part of the treatment, wash them again after using the cream.

For an adult

Do not worry if you find you need a little more or less than this. It is only a rough guide.

For a child

Number of fingertip units needed					
Child's	**Face**	**Arm**	**Leg**	**Front**	**Back**

age	and neck	and hand	and foot		including buttocks
3-6 months	1	1	1 ½	1	1 ½
1-2 years	1 ½	1 ½	2	2	3
3-5 years	1 ½	2	3	3	3 ½
6-10 years	2	2 ½	4 ½	3 ½	5

- Do not use on children younger than 12 years unless advised by a doctor.
- If the condition worsens or does not improve within 7 days, consult a doctor.
- Once the condition improves, reduce both the amount applied and the frequency of application to the minimum necessary to relieve symptoms.
- Do not use every day for more than 4 weeks at a time.

If you apply Eumovate to your face
You should only apply the cream to your face if your doctor tells you to. The cream should not be used for too long as the skin on your face thins easily. **Do not let the cream get into your eyes.**

If you use more Eumovate than you should
If you apply a lot or if a lot is accidentally swallowed, it could make you ill. Talk to your doctor or go to hospital as soon as possible.

If you forget to use Eumovate
If you forget to apply your cream, apply it as soon as you remember. If it is close to the time you are next meant to apply it, wait until this time.

If you stop using Eumovate
If you use Eumovate regularly make sure you talk to your doctor before you stop using it as your condition may get worse if stopped suddenly.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects
Like all medicines, this medicine can cause side effects, although not everybody gets them.

Stop using Eumovate and tell your doctor immediately if:
- you find that your skin condition gets worse, you develop a generalised rash or your skin becomes swollen during treatment. You may be allergic to the cream, have an infection or need other treatment.

Other side effects you may notice when using Eumovate include:

Very rare: may affect up to 1 in 10,000 people

- an increased risk of skin infection.
- an allergic skin reaction where the cream is applied.
- a feeling of burning, irritation, itching or pain where the cream is applied.
- rash, itchy bumpy skin or redness of the skin.
- increased hair growth and changes in skin colour
- thinning of your skin and it may also damage more easily
- weight gain, rounding of the face
- delayed weight gain or slowing of growth in children
- bones can become thin, weak and break easily
- cloudy lens in the eye (cataract) or increased pressure in eye (glaucoma)
- increased blood sugar levels or sugar in the urine
- high blood pressure
- a decrease in the level of the hormone cortisol in your blood

Not Known: frequency cannot be estimated from the available data

- blurred vision

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. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Eumovate

- Keep this medicine out of the sight and reach of children.
- Do not use this medicine after the expiry date which is stated on the tube or carton after (EXP).
- Store as directed on the outer package
- Do not throw away any medicines via wastewater or household waste. 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 Eumovate cream contains

- The active ingredient is clobetasone butyrate. Each 1 g contains 0.5 mg of clobetasone butyrate (0.05% w/w).
- The other ingredients are glycerol, glycerol monostearate, cetostearyl alcohol (see section 2), beeswax substitute 6621, Arlacel 165, dimeticone 20, chlorocresol (see section 2), sodium citrate, citric acid monohydrate and purified water

What Eumovate looks like and contents of the pack
Within each carton is a tube with a plastic screw cap.

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包裝單張: 使用者須知

悠美膚 (Eumovate)乳膏
clobetasone butyrate

在使用本藥物前，請仔細閱讀本單張，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，請諮詢您的醫生或藥劑師。
- 本藥物為醫生專門為您處方。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損害。
- 如果您出現了任何副作用，請告知您的醫生或藥劑師。這包括未在本說明書中列出的任何可 能的副作用。參見第4部分。

本單張包括:

1. 悠美膚 (Eumovate)是什麼及有何用途
悠美膚 (Eumovate)含有一種被稱為clobetasone butyrate的藥物。它屬於一種稱為類固醇的藥物。它有助於減輕皮膚刺激並且消腫。

悠美膚 (Eumovate)用於：
- 減輕某些皮膚問題引起的發紅和痕癢的狀況，用於控制一些輕微的皮膚問題，例如濕疹， 皮膚炎，尿布疹或昆蟲叮咬反應。
- 減輕外耳發炎

2. 在使用悠美膚 (Eumovate)前，您需要了解哪些資訊
如有以下情況，切勿使用悠美膚 (Eumovate)：
- 如果您對clobetasone butyrate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）
- 治療以下任何皮膚問題，本藥物會令情況加重：
  - 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））
  - 皮膚未發炎，卻出現痕癢

如果任何上述情況適用於您，請勿使用本藥物。如果您有不明白的地方，請在使用悠美膚 (Eumovate)前諮詢您的醫生或藥劑師。

警告和注意事項
如果您有以下情況，請在使用悠美膚 (Eumovate)前諮詢您的醫生或藥劑師：
- 您曾對另一種類固醇出現過敏情況。
- 使用本藥物治療慢性腿部潰瘍，因為您出現局部過敏反應或感染的風險會更高。

- 您的醫生曾告知您要以不透氣的敷料下使用乳膏，包括嬰兒尿布。為了預防感染，在換上新　敷料前，要清潔皮膚。不透氣的敷料會讓本藥物中的活性成份更容易滲透皮膚。有可能會意　外地使用過多的乳膏。
- 在皮膚較薄處使用本藥物，例如面部，皮膚較薄容易吸收過多份量。如在面部使用，不應以　敷料或繃帶遮住用藥部位。
- 長時間在面部使用，因為本藥物會令皮膚變薄

- 在皮膚破損處或皮膚褶皺下使用本乳膏。
- 在眼部周圍或眼瞼上使用本藥物，因為如果藥物不斷進入眼睛，可能會導致白內障或青光　眼。
- 意外吞服大量悠美膚 (Eumovate)，請用大量清水漱口並**立即**聯繫醫生或藥劑師尋求意見
- 在使用本藥物的過程中出現感染（參見第4部分：可能出現的副作用） 如

果出現視野模糊或其他視覺障礙的情況，請諮詢您的醫生。

兒童

- 正常情況下，十二歲以下的兒童之療程不應多於七天
- 長時間每天使用本藥物會影響兒童成長。不建議連續每天使用超過四週

如果您不確定上述任何情況是否適用於您，請在使用本藥物前諮詢您的醫生或藥劑師。

其他藥物與悠美膚 (Eumovate)

如果您正在服用，或近期服用過，或可能會服用任何其他藥物，尤其是如果您正在服用 ritonavir 和 itraconazole 接受治療，請將此告知您的醫生或藥劑師。

懷孕、哺乳和生育

如果您已經懷孕或在哺乳期中，可能懷孕或計劃懷孕，請在使用本藥物前諮詢您的醫生或藥劑　師。

悠美膚 (Eumovate)中含有 chlorocresol 和 cetostearyl alcohol。

Chlorocresol 可能會對皮膚造成過敏反應。Cetostearyl alcohol 可能會造成局部皮膚反應（例如，接觸性皮炎）

當使用悠美膚 (Eumovate)，不要吸煙或靠近火種 ， 因為有機會做成嚴重灼傷。當纖維物質(衣服， 床單，敷料等) 與此產品接觸會更容易產生燃燒及嚴重火災的危機。清洗衣服與床單可以減少此產品的剩餘數量， 但不能被完全除去。

3. 如何使用悠美膚 (Eumovate)

請始終嚴格按照醫生指示用藥。如果您有不明白的地方，請諮詢您的醫生或藥劑師。

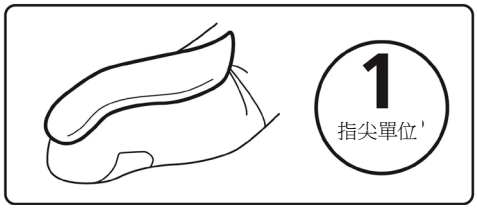
使用本藥物

- 一般情況下，每天使用悠美膚 (Eumovate)2次。隨著皮膚情況有所好轉，用藥量可適當減少
- 該乳膏只可外用於皮膚上。
- 在沒有諮詢醫生的情況下，切勿長時間大範圍地使用本藥物（例如連續數週或數月每天使用）。
- 如果您還在使用潤膚劑（保濕乳霜），請先等待悠美膚　(Eumovate)被皮膚充分吸收後再使用潤膚劑。
- 如果您為他人塗抹本藥物，請確保您在接觸藥物後洗手或用藥前戴上一次性手套。

- 如果您的皮膚問題在用藥4周後仍沒有改善，請諮詢您的醫生。

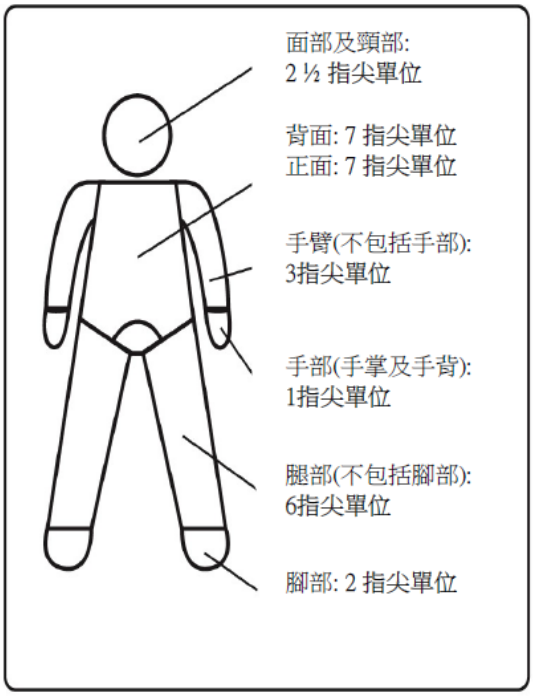
用藥指南

1. 清洗雙手。
2. 將少量藥物薄薄地塗於患處，輕揉直至藥物被皮膚吸收，完全消失。您可以用指尖衡量用藥　量。對於兒童，您要減少用藥量，但是仍然要用成人的手指來衡量出指尖單位。下圖示意了　一個指尖單位的劑量。



3. 除非您要將本藥物塗於自己手上作為治療的一部分，否則請在用藥結束後再次洗手。

成人



如果您發現劑量略多或略少，請勿擔心。這是一個粗略指引。

兒童

需要的指尖單位數量					
兒童的年齡	**面部和頸部**	**手臂和手**	**腿部和腳部**	**正面**	**背面包括臀部**
3-6個月	1	1	1 ½	1	1 ½
1-2歲	1 ½	1 ½	2	2	3
3-5歲	1 ½	2	3	3	3 ½
6-10歲	2	2 ½	4 ½	3 ½	5

- 除非有醫生指引，否則不得對未滿12歲的兒童使用本藥物
- 如果病情在七天內惡化或沒有改善，請諮詢你的醫生
- 一旦病情有所改善，可減少用藥份量和次數，用最少劑量緩解症狀
- 不要連續每天使用超過四週

如果您要將悠美膚 (Eumovate)用於面部
只有在醫生指示下，您才能將本乳膏用於面部。療程不得過長，因為面部皮膚很容易變薄。**切勿讓本乳膏進入眼睛。**

如果您使用了過量的悠美膚 (Eumovate)
如果您使用了過量的悠美膚 (Eumovate)，或不小心吞服本藥物，您可能會因此產生不適。請立即諮詢您的醫生或前往醫院就醫。

如果您忘記使用悠美膚 (Eumovate)
如果您忘記使用悠美膚 (Eumovate)，請在記起時立即使用。如果此時接近於下次用藥時間，請等到下次再用藥。

如果您停止使用悠美膚 (Eumovate)
如果您一直在按時使用悠美膚 (Eumovate)，那麼在停止用藥前，請諮詢您的醫生，因為如果您突然停止用藥，您的病情可能會惡化。

如果您對本藥物的使用有任何進一步的疑問，請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。

如果出現以下情況，請停止使用悠美膚 (Eumovate)並立即諮詢您的醫生：
- 發現皮膚問題惡化，出現周身皮疹或在治療期間皮膚腫脹。您可能對本乳膏過敏，出現感染 或需要接受其他治療。

您在使用悠美膚 (Eumovate)時可能會注意到的其他副作用：
極為罕見（每10,000個人中最多有1人可能會受此影響）
- 增加感染機會
- 用藥處出現過敏反應
- 用藥處感到灼燒、刺激、痕癢或疼痛
- 皮疹，發癢，發紅
- 增加頭髮生長，膚色改變
- 皮膚變薄，而且可能更容易受損
- 體重增加，面部變圓
- 兒童體重增加緩慢或生長發育緩慢
- 骨骼變得脆弱，並更容易骨折
- 晶狀體渾濁（白內障）或眼壓增高（青光眼）
- 血糖或尿糖升高
- 高血壓
- 減少皮質醇在血液的濃度

未知（根據現有數據未能估計副作用出現頻率）

- 視力模糊

如果您出現了任何副作用，請告知您的醫生或藥劑師。這包括未在本說明書中列出的任何可能的 副作用。

5. 如何存放悠美膚 (Eumovate)

- 請將本藥物放在兒童無法看見並觸及的地方。
- 如果悠美膚 (Eumovate)放置超過了藥膏管和包裝盒上印制的有效期，切勿使用。
- 請按照外包裝上的說明進行存放。
- 請勿將任何藥物當一般家居廢物或直接經排污系統丟棄。請向您的藥劑師查詢如何丟棄不 用的藥物。這將幫助保護環境。

6. 包裝內容和其他資訊

悠美膚(Eumovate) 乳膏含有哪些成份

- 活性成分為 clobetasone butyrate。每 1 克藥物還有 0.5 毫克 clobetasone butyrate (0.05% w/w)。
- 其他成分有 glycerol、glycerol monostearate、cetostearyl alcohol (參見第 2 部分)、beeswax substitute 6621、Arlacel 165、dimeticone 20、 chlorocresol (參見第 2 部分)、sodium citrate 、citric acid monohydrate 和 purified water。

悠美膚(Eumovate)的外觀和包裝內容

每盒中含有一管帶有塑膠蓋的乳膏。

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