

## **Dermovate Cream and Ointment**

### **Presentation**

Dermovate Cream and Ointment each contain 0.05% w/w clobetasol propionate. The water-miscible cream and the paraffin-based ointment are both white in appearance.

#### Excipients:

Dermovate Cream: Cetostearyl alcohol, Glyceryl monostearate, Arlacel 165, Beeswax substitute 6621, Propylene glycol, Chlorocresol, Sodium citrate, Citric acid monohydrate, Purified water

Dermovate Ointment: Propylene glycol, Sorbitan sesquioleate, White soft paraffin

### **Indications**

Dermovate is a very potent topical corticosteroid indicated for adults, elderly and children over 1 year for the short-term treatment only of more resistant inflammatory and pruritic manifestations of steroid responsive dermatoses unresponsive to less potent corticosteroids. These include the following:

- Psoriasis (excluding widespread plaque psoriasis)
- Recalcitrant dermatoses
- Lichen planus
- Discoid lupus erythematosus
- Other skin conditions which do not respond satisfactorily to less potent steroids

### **Dosage and Administration**

Route of administration: Cutaneous

Creams are especially appropriate for moist or weeping surfaces.

Ointments are especially appropriate for dry, lichenified or scaly lesions.

#### **Adults, Elderly and Children over 1 year**

Apply thinly and gently rub in using only enough to cover the entire affected area once or twice a day until improvement occurs (in the more responsive conditions this may be within a few days), 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.

Repeated short courses of Dermovate may be used to control exacerbations.

In more resistant lesions, especially where there is hyperkeratosis, the effect of Dermovate can be enhanced, if necessary, by occluding the treatment area with polythene film. Overnight occlusion only is usually adequate to bring about a satisfactory response. Thereafter improvement can usually be maintained by application without occlusion.

If the condition worsens or does not improve within 2-4 weeks, treatment and diagnosis should be re-evaluated.

Treatment should not be continued for more than 4 weeks. If continuous treatment is necessary, a less potent preparation should be used.

The maximum weekly dose should not exceed 50gms/week.

Therapy with Dermovate 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 Dermovate.

### **Recalcitrant dermatoses**

#### **Patients who frequently relapse**

Once an acute episode has been treated effectively with a continuous course of topical corticosteroid, intermittent dosing (once daily, twice weekly, without occlusion) may be considered. This has been shown to be helpful in reducing the frequency of relapse.

Application should be continued to all previously affected sites or to known sites of potential relapse. This regimen should be combined with routine daily use of emollients. The condition and the benefits and risks of continued treatment must be re-evaluated on a regular basis.

### **Paediatric population**

Dermovate is contraindicated in children under one year of age.

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.

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

### **Duration of treatment for children and infants**

Courses should be limited if possible to five days and reviewed weekly. Occlusion should not be used.

### **Application to the face**

Courses should be limited to five days if possible and occlusion should not be used.

### **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 Dermovate:

- Untreated cutaneous infections
- Rosacea
- Acne vulgaris
- Pruritus without inflammation
- Perianal and genital pruritus
- Perioral dermatitis

Dermovate is contraindicated in dermatoses in children under one year of age, including dermatitis and nappy eruptions.

### **Special Warnings and Precautions for Use**

Dermovate should be used with caution in patients with a history of local hypersensitivity to other corticosteroids or to any of the excipients in the preparation. 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 (see section *Undesirable Effects*).

Dermovate Ointment contains propylene glycol which may cause skin irritation.

Dermovate Cream contains:

- propylene glycol which may cause skin irritation.
- cetostearyl alcohol which may cause local skin reactions (e.g. contact dermatitis).
- chlorocresol which may cause allergic 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.

Visual disturbance has been reported by patients using systemic and/or topical corticosteroids. If a patient has blurred vision or other visual disturbances, consider evaluation of possible causes which may include cataract, glaucoma or central serous chorioretinopathy.

#### **Paediatric population**

In infants and children under 12 years of age, long-term continuous topical corticosteroid therapy should be avoided where possible, as adrenal suppression can occur

Children are more susceptible to develop atrophic changes with the use of topical corticosteroids.

#### **Duration of treatment for children and infants**

Courses should be limited if possible to five days and reviewed weekly. Occlusion should not be used.

#### **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 corticosteroids should be used with caution in psoriasis as rebound relapses, development of tolerances, 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.

#### **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.

#### **Application to the face**

Application to the face is undesirable as this area is more susceptible to atrophic changes. If used on the face, treatment should be limited to only 5 days.

#### **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. If Dermovate does enter the eye, the affected eye should be bathed in copious amounts of water.

#### **Interactions**

Co-administered drugs that can inhibit CYP3A4 (eg ritonavir and 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**

## Pregnancy

There are limited data from the use of Dermovate 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. Administration of Dermovate 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 Dermovate during lactation should only be considered if the expected benefit to the mother outweighs the risk to the infant.

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

## Fertility

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

There are no data in humans to evaluate the effect of topical corticosteroids on fertility. Clobetasol administered subcutaneously to rats had no effect upon mating performance; however, fertility was decreased at the highest dose.

## Effects on ability to drive and use machines

**Effects on ability to drive and use machines**  
There have been no studies to investigate the effect of clobetasol 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 clobetasol.

## Undesirable effects

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

## Post-marketing data

## Infections and Infestations

## 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, hyperglycaemia/glucosuria, hypertension, increased weight/obesity, decreased endogenous cortisol levels, alopecia, trichorrhexis
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## Eye Disorders

Very rare Cataract, central serous chorioretinopathy, glaucoma

## **Skin and Subcutaneous Tissue Disorders**

Common	Pruritus, local skin burning /skin pain
Uncommon	Skin atrophy*, striae*, telangiectasias*
Very rare	Skin thinning*, skin wrinkling*, skin dryness*, pigmentation changes*, hypertrichosis, exacerbation of underlying symptoms, allergic contact dermatitis/dermatitis, pustular psoriasis, erythema, rash, urticaria, acne

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

## **General Disorders and Administration Site Conditions**

Very rare	Application site irritation/pain
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## **Overdosage**

### Symptoms and signs

Topically applied Dermovate 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 (see section *Undesirable Effects*).

### Treatment

In the event of overdose, Dermovate 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

Pharmacotherapeutic group: Corticosteroids, very potent (group IV)

ATC code: D07AD

### 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.

### Pharmacokinetic properties

#### Absorption

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.

Mean peak plasma clobetasol propionate concentrations of 0.63 ng/ml occurred in one study eight hours after the second application (13 hours after an initial application) of 30 g clobetasol propionate 0.05% ointment to normal individuals with healthy skin. Following the application of a

second dose of 30 g clobetasol propionate cream 0.05% mean peak plasma concentrations were slightly higher than the ointment and occurred 10 hours after application.

In a separate study, mean peak plasma concentrations of approximately 2.3 ng/ml and 4.6 ng/ml occurred respectively in patients with psoriasis and eczema three hours after a single application of 25 g clobetasol propionate 0.05% ointment.

#### Distribution

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**

#### Carcinogenesis / Mutagenesis

#### Carcinogenesis

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

#### Genotoxicity

Clobetasol propionate was not mutagenic in a range of in vitro bacterial cell assays.

#### Reproductive Toxicology

#### Fertility

In fertility studies, subcutaneous administration of clobetasol propionate to rats at doses of 6.25 to 50 micrograms/kg/day produced no effects on mating, and fertility was only decreased at 50 micrograms/kg/day.

#### Pregnancy

Subcutaneous administration of clobetasol propionate to mice ( $\geq$ 100 micrograms/kg/day), rats (400 micrograms/kg/day) or rabbits (1 to 10 micrograms/kg/day) during pregnancy produced foetal abnormalities including cleft palate and intrauterine growth retardation.

In the rat study, where some animals were allowed to litter, developmental delay was observed in the F1 generation at  $\geq$ 100 micrograms/kg/day and survival was reduced at 400 micrograms/kg/day. No treatment-related effects were observed in F1 reproductive performance or in the F2 generation.

### **Incompatibilities**

None reported

**Shelf-life**

The expiry date is indicated on the packaging.

**Special precaution for storage**

Please refer to the outer packaging

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## Package Leaflet: Information for the User

### Dermovate Cream and Ointment clobetasol propionate

**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 Dermovate is and what it is used for
- 2 What you need to know before you use Dermovate
- 3 How to use Dermovate
- 4 Possible side effects
- 5 How to store Dermovate
- 6 Contents of the pack and other information

#### 1. What Dermovate is and what it is used for

Dermovate contains a medicine called clobetasol propionate. It belongs to a group of medicines called steroids. It helps to reduce swelling and irritation.

Dermovate is used to help reduce the redness and itchiness of certain skin problems. These skin problems include:

- frequently relapsing eczema
- psoriasis (thickened patches of inflamed, red skins, often covered by silvery scales), excluding widespread plaque psoriasis
- lichen planus ( a skin disease that causes itchy , reddish-purple, flat-topped bumps on the wrists, forearms or lower legs)
- 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)
- dermatitis and other skin conditions that have not responded to milder steroid creams or ointments.

#### 2. What you need to know before you use Dermovate

##### Do not use Dermovate:

- if you are allergic (hypersensitive) to clobetasol propionate or any of the other ingredients of this medicine (listed in Section 6 *Contents of the pack and other information*)
- on a child under 1 year of age
- to treat any of the following skin problems, it could make them worse:
  - acne
  - severe flushing of skin on and around your nose (rosacea)
  - spotty red rash around your mouth (perioral dermatitis)
  - itching around your anus or genitals (penis or vagina)
  - infected skin (unless the infection is being treated with an anti-infective medicine at the same time)
  - itchy skin which is not inflamed
  - widespread plaque psoriasis, except single lesions

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

#### Warnings and precautions

Talk to your doctor or pharmacist before using Dermovate if:

- you have previously had an allergic reaction with another steroid
- you are applying the cream/ointment under an airtight dressing, including a child's nappy. These dressings make it easier for the active ingredient to pass through the skin. It is possible to accidentally end up using too much cream/ointment.
- make sure that the skin is cleansed before a fresh dressing is applied to prevent infections
- you are applying the cream/ointment on broken or damaged skin or within the skin folds.
- you are applying to a large surface area
- you have psoriasis, your doctor will want to see you more often.
- you are using for a chronic leg ulcer as you may be at increased risk of local allergic reaction or infection.
- you are applying near eyes or on eyelids, as cataracts or glaucoma may result if the cream/ointment repeatedly enters the eye.
- you experience blurred vision or other visual disturbances
- you are applying to thin skin such as the face, as Dermovate may cause skin thinning. Use on the face should be limited to 5 days. Dressings or bandages should not be used on the face where the cream is applied.

If an infection develops during the use of this medicine, talk to your doctor or pharmacist.

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

### **Children**

- Do not use this medicine in children under 1 year of age.
- Avoid continuous treatment for a long period of time in infants and children over 1 year of age, as their skin is thinner than adults and as a result may absorb larger amounts.
- Use on children should be limited to 5 days and reviewed weekly.
- Dressings or bandages should not be used on children where the cream is applied.

### **Other medicines and Dermovate**

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.

If you do use Dermovate when breast-feeding, do not use it on your breast area to ensure that the baby does not accidentally get Dermovate in their mouth.

### **Dermovate Cream contains propylene glycol, cetostearyl alcohol and chlorocresol**

Propylene glycol may cause skin irritation. Cetostearyl alcohol may cause local skin reactions (e.g. contact dermatitis). Chlorocresol may cause allergic reactions.

### **Dermovate Ointment contains propylene glycol**

Propylene glycol may cause skin irritation.

### **3. How to use Dermovate**

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 a thin layer of Dermovate once or twice a day. This may be reduced as your skin begins to get better, or stopped when it is better. Your doctor may prescribe a weaker steroid for you to use instead.
- If you are also using an emollient (moisturizer), allow time for Dermovate to be absorbed into your skin before applying the emollient.
- This cream/ointment is for use on your skin only.
- Do not use for more than 4 weeks without talking to your doctor. If you need treatment for a long time, your doctor may decide you need to use a milder cream or ointment.
- If your skin problem worsens or does not improve within 2 to 4 weeks, talk to your doctor.
- The germs that cause infections like the warm and moist conditions under dressings. If directed to cover the treated area with a dressing, always clean the skin before a fresh dressing is put on to help prevent infection of the skin beneath the dressing.
- If you are applying the cream/ointment on someone else make sure you wash your hands after use or wear disposable plastic gloves.

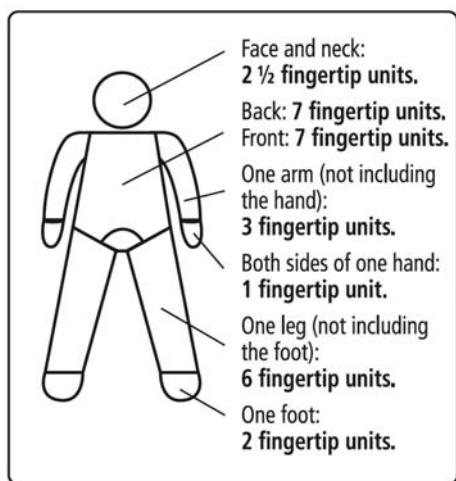
#### Guidance on how to apply the cream/ointment

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 Dermovate to use with your fingertip. For children you will need to use less cream/ointment 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/ointment to your hands as a part of the treatment, wash them again after using the cream/ointment.

#### 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 aged 1 – 10

Child's age	Number of fingertip units needed				
	Face and neck	Arm and hand	Leg and foot	Front	Back including buttocks
1-2	1 ½	1 ½	2	2	3

years					
3-5 years	1 ½	2	3	3	3 ½
6-10 years	2	2 ½	4 ½	3 ½	5

### Use in children

- Do not use this medicine on children under 1 year of age.
- It is especially important in children not to exceed the prescribed amount.
- A course of treatment for a child over the age of 1 year should not normally last more than 5 days unless your doctor has told you to use it for longer. The doctor may want to see the child every week, whilst using the cream/ointment.
- Dressings or bandages should not be used on children where the cream is applied.

### If you have psoriasis

If you have thick patches of psoriasis on your elbows or knees, your doctor may suggest applying the cream/ointment under an airtight dressing. It will only be at night to help the cream/ointment to start working. After a short period of time you will then apply the cream/ointment as normal.

### If you apply Dermovate to your face

You should only apply the cream/ointment to your face if your doctor tells you to. It should be limited to only 5 days, as the skin on your face thins easily. Dressings or bandages should not be used on the face where the cream is applied. **Do not let the cream/ointment get into your eyes.** If it does, wash it out with plenty of water.

### If you use more Dermovate than you should

If you apply too much or if accidentally swallowed, it could make you ill. Talk to your doctor or go to hospital as soon as possible.

### If you forget to use Dermovate

If you forget to apply your cream/ointment, 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. Do not apply extra Dermovate to make up for a missed dose.

### If you stop using Dermovate

If you use Dermovate 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 Dermovate and tell your doctor immediately if:

- you find that your skin problem gets worse, you develop a generalized rash or your skin becomes swollen during treatment. You may be allergic to the cream/ointment, have an infection or need other treatment.
- you have psoriasis and get raised bumps with pus under the skin. This can happen during or after the treatment and is known as pustular psoriasis.

### Other side effects you may notice when using Dermovate include:

#### Common (may affect up to 1 in 10 people)

- A feeling of burning, pain, irritation or itching where the cream/ointment is applied.

#### Uncommon (may affect up to 1 in 100 people)

- Skin thinning, the may cause stretch marks.
- Blood vessels under the surface of your skin may become more noticeable.

### **Very Rare (may affect up to 1 in 10,000 people)**

Use of Dermovate 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
- skin wrinkling
- skin dryness
- changes to the colour of your skin
- increased body hair
- hair loss/lack of hair growth/damaged looking hair

Other very rare skin reactions that may occur are:

- allergic reaction at the site of application
- worsening of condition
- application site irritation/pain
- 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
- acne

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)
- vision problems caused by detachment of the retina in the eye (central serous chorioretinopathy)
- 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

### **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 Dermovate**

- 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 to protect the environment.

### **6. Contents of the pack and other information**

#### **What Dermovate cream contains**

- The active ingredient is clobetasol propionate. Each 1 g contains 0.5 mg of clobetasol propionate (0.05% w/w).
- The other ingredients are cetostearyl alcohol, glyceryl monostearate, arlacet 165, beeswax substitute 6621, propylene glycol, chlorocresol, sodium citrate, citric acid monohydrate and purified water.

#### **What Dermovate ointment contains**

- The active ingredient is clobetasol propionate. Each 1 g contains 0.5 mg of clobetasol propionate (0.05% w/w).
- The other ingredients are propylene glycol, sorbitan sesquioleate and white soft paraffin.

#### **What Dermovate 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

特美膚 (Dermovate)乳膏及油膏  
clobetasol propionate

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服用。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. 特美膚(Dermovate)是什麼及有何用途
2. 在使用特美膚(Dermovate)前，您需要了解哪些資訊
3. 如何使用特美膚(Dermovate)
4. 可能出現的副作用
5. 如何存放特美膚(Dermovate)
6. 包裝內容和其他資訊

### 1. 特美膚(Dermovate)是什麼及有何用途

特美膚(Dermovate)含有一種被稱為clobetasol propionate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。

特美膚(Dermovate)被用於減輕某些皮膚問題引起的發紅和痕癢的狀況。這些皮膚問題包括：

- 經常復發的濕疹
- 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)，不包括大面積的斑塊狀銀屑病
- 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)
- 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)
- 皮炎以及對藥效較溫和的類固醇乳膏/油膏具有耐受性的其他皮膚病

### 2. 在使用特美膚(Dermovate)前，您需要了解哪些資訊

如有以下情況，切勿使用特美膚(Dermovate)：

- 如果您對clobetasol 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）
- 未滿1歲的兒童
- 治療以下任何皮膚問題，本藥物會令情況加重：
  - 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（口周皮炎 (perioral dermatitis)）
  - 肛門和生殖器（陰莖或陰道）周圍痕癢
  - 皮膚感染（除非同時在使用抗感染藥物治療感染）
  - 皮膚未發炎，卻出現痕癢
  - 大面積斑塊狀銀屑病，單一患處除外

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，請在使用特美膚(Dermovate)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，請在使用特美膚(Dermovate)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。
- 在不透氣的敷料下使用乳膏/油膏，包括嬰兒尿布。這些不透氣的敷料會讓本藥物中的活性成份更容易滲透皮膚。有可能會使用過多的乳膏/油膏。
- 在換上新敷料前，要清潔皮膚，防止感染。
- 在皮膚破損處或皮膚褶皺下使用本乳膏/油膏。
- 在較大的皮膚面積上使用本乳膏/油膏。
- 您患有銀屑病（psoriasis），您的醫生會希望您能多覆診。
- 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。
- 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。
- 出現視野模糊或其他視覺障礙的情況。
- 在皮膚較薄處，例如面部，使用本藥物，因為特美膚(Dermovate)可能會讓皮膚變薄。如果要在面部用藥，療程應限制在5天以內。如果在面部使用本藥物，切勿用敷料或繃帶遮住用藥部位。

如果在使用本藥物的過程中出現感染，請諮詢您的醫生或藥劑師。

如果您無法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。

### **兒童**

- 未滿1歲的兒童不得使用本藥物。
- 對於嬰兒和年滿1歲的兒童，要避免長期使用本藥物對其進行治療，因為他們的皮膚厚度比成年人薄，會因此吸收更多的藥物。
- 如果兒童使用本藥物，療程不得超過5天並需要每周進行檢查。
- 如果兒童使用本藥物，不得用敷料或繃帶遮住用藥部位。

### **其他藥物與特美膚(Dermovate)**

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。

如果您在哺乳期的確要使用特美膚(Dermovate)，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。

### **特美膚(Dermovate)乳膏中含有propylene glycol、cetostearyl alcohol和chlorocresol**

Propylene glycol可能會對皮膚造成刺激。Cetostearyl alcohol可能會造成局部皮膚反應（例如，接觸性皮炎）Chlorocresol可能會引起過敏反應。

### **特美膚(Dermovate)油膏含有propylene glycol**

Propylene glycol可能會對皮膚造成刺激。

### **3. 如何使用特美膚(Dermovate)**

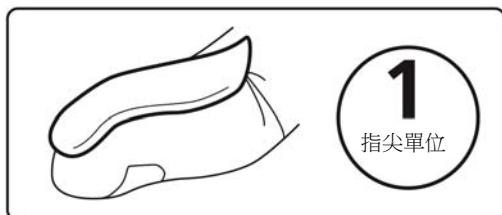
請始終嚴格按照醫生指示用藥。如果您有不明白的地方，請諮詢您的醫生或藥劑師。

## 使用本藥物

- 一般情況下，請將少量特美膚(Dermovate)薄薄地塗於患處，每天1至2次。隨著皮膚情況有所好轉，用藥量可適當減少或在好轉後停止用藥。您的醫生可能會讓您使用一種較為溫和的類固醇藥物作為替代。
- 如果您還在使用潤膚劑（保濕乳霜），請先等待特美膚(Dermovate)被皮膚充分吸收後再使用潤膚劑。
- 該乳膏/油膏只可外用於皮膚上。
- 在沒有諮詢醫生的情況下，切勿用藥超過4周。如果您需要接受長期治療，您的醫生可能會決定讓您使用一種更為溫和的乳膏/油膏。
- 如果您的皮膚問題惡化或在2至4周內沒有改善，請諮詢您的醫生。
- 造成感染的細菌喜歡敷料下溫暖、潮濕的環境。如果醫生指示用敷料遮蓋治療區域，請務必先清潔皮膚，然後再用乾淨的敷料進行遮蓋，防止皮膚在敷料下出現感染。
- 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。

## 用藥指南

- 清洗雙手。
- 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。



- 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。

## 成人用藥



如果您發現劑量略多或略少，請勿擔心。這是一個粗略指引。

## 對於年齡在1 - 10歲的兒童

兒童的 年齡	需要的指尖單位數量				
	面部 和 頸部	手臂 和 手	腿部 和 腳部	正面	背面 包括 臀部
1-2	1 1/2	1 1/2	2	2	3

歲					
3-5 歲	1 $\frac{1}{2}$	2	3	3	3 $\frac{1}{2}$
6-10 歲	2	2 $\frac{1}{2}$	4 $\frac{1}{2}$	3 $\frac{1}{2}$	5

### 兒童用藥

- 不得對未滿1歲的兒童使用本藥物。
- 兒童用藥不得超過處方中規定的劑量，這一點十分重要。
- 對於年齡超過1歲的兒童，除非醫生告知用藥會持續更長時間，否則他們的療程一般不得超過5天。在使用本藥物期間，您的孩子可能要每周覆診，接受檢查。
- 如對兒童使用本藥物，不得用敷料或繃帶遮住用藥部位。

### 如果您患有銀屑病 (psoriasis)

如果您的肘部或膝蓋處有銀屑病 (psoriasis) 造成的變厚的斑疹，您的醫生可能會建議在塗抹該乳膏/油膏後用不透氣的敷料覆蓋。在晚上敷上才會有助於本乳膏/油膏發揮藥效。在不久後，您將照常使用本乳膏/油膏。

### 如果您要將特美膚(Dermovate)用於面部

只有在醫生指示下，您才能將本乳膏/油膏用於面部。療程不得超過5天，因為面部皮膚很容易變薄。如果在面部使用本藥物，不得用敷料或繃帶遮住用藥部位。切勿讓本乳膏/油膏進入眼睛。如果藥物進入眼睛，請用大量清水沖洗。

### 如果您使用了過量的特美膚(Dermovate)

如果您使用了過量的特美膚(Dermovate)，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。

### 如果您忘記使用特美膚(Dermovate)

如果您忘記使用特美膚(Dermovate)，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。

請勿因為忘記用藥而一次性使用較大劑量。

### 如果您停止使用特美膚(Dermovate)

如果您一直在按時使用特美膚(Dermovate)，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，請停止使用特美膚(Dermovate)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/油膏過敏，出現感染或需要接受其他治療。
- 患有銀屑病而且在皮下出現凸起的化膿腫塊。這種情況會出現在治療當中或治療結束之後，這被稱為膿皰性銀屑病 (pustular psoriasis)。

### 您在使用特美膚(Dermovate)時可能會注意到的其他副作用：

### 常見（每10個人中最多有1人可能會受此影響）

- 用藥處感到灼燒、疼痛、刺激或痕癢。

### 不常見（每100個人中最多有1人可能會受此影響）

- 皮膚變薄，這可能會造成伸展紋。
- 皮下血管會變得更加清晰可見。

### 極為罕見（每10,000個人中最多有1人可能會受此影響）

長期使用特美膚(Dermovate)或在不透氣敷料遮蓋的情況下使用特美膚(Dermovate)，可能會造成以下症狀：

- 體重增加
- 滿月臉，面部變圓
- 肥胖症
- 皮膚變薄
- 皮膚起皺
- 皮膚乾燥
- 膚色改變
- 體毛增多
- 脫髮/頭髮生長不足/頭髮受損

其他可能出現的罕見皮膚反應有：

- 用藥處出現過敏反應
- 痘情惡化
- 用藥處出現刺激感/疼痛感
- 發紅
- 皮疹或風疹
- 如果您患有銀屑病 (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
- 暗瘡

對於兒童，也要注意以下症狀：

- 體重增加延遲
- 生長發育緩慢

在血液測試中或在醫生進行的檢查中可能會出現的極為罕見的副作用：

- 血液中皮質醇水平下降
- 血糖或尿糖升高
- 高血壓
- 晶狀體渾濁（白內障）
- 眼壓增高（青光眼）
- 因視網膜脫落而導致的視力問題（中心性漿液性脈絡膜視網膜病變）
- 礦物質逐漸流失導致骨骼變得脆弱（骨質疏鬆症（osteoporosis）；在醫學檢查結束後可能還需接受額外測試以確認您是否存在這一情況

## 報告副作用

如果您出現了任何副作用，請告知您的醫生或藥劑師。這包括未在本手冊中列出的任何可能的副作用。透過報告副作用，您能幫助提供更多有關此藥物安全性的資料。

## 5. 如何存放特美膚(Dermovate)

- 請將本藥物放在兒童無法看見並觸及的地方。
- 如果特美膚(Dermovate)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

### 特美膚(Dermovate)乳膏有哪些成份

- 活性成分為clobetasol propionate。每1克乳膏/油膏含有0.5毫克的clobetasol propionate (0.05% w/w)。
- 其他成份有cetostearyl alcohol、glyceryl monostearate、arlacel 165、beeswax substitute 6621、propylene glycol、chlorocresol、sodium citrate、citric acid monohydrate和purified water。

### 特美膚(Dermovate)油膏有哪些成份

- 活性成分為clobetasol propionate。每1克乳膏/油膏含有0.5毫克的clobetasol propionate (0.05% w/w)。
- 其他成份有propylene glycol、sorbitan sesquioleate以及white soft paraffin。

### 特美膚(Dermovate)的外觀和包裝內容

每盒中含有一管帶有塑膠蓋的乳膏/油膏。

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