Dermovate Scalp Application

Presentation
Dermovate Scalp Application contains clobetasol propionate 0.05% w/w.
Excipients: Carbomer, Isopropyl Alcohol, Sodium Hydroxide, Purified Water

Indications
Dermovate is a very potent topical corticosteroid which is indicated for use in short courses for conditions which do not respond satisfactorily to less active steroids.
It is indicated for use in steroid responsive dermatoses of the scalp such as:
- Psoriasis.
- Recalcitrant dermatoses.

Dosage and Administration
Route of administration: Topical, on the scalp.

Owing to the flammable nature of the product, Dermovate Scalp Application should be kept away from open fire and flames and all sources of ignition, including smoking, during and immediately after use.

Adults, Elderly and Children over 1 year
A small quantity of Dermovate should be applied to the scalp night and morning until improvement is noticeable. It may then be possible to sustain improvement by applying once a day, or less frequently.

Paediatric population
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 a few days and reviewed weekly.

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
Infections of the scalp.
Hypersensitivity to the active substance or any of the excipients listed.
Dermatoses in children under one year of age, including dermatitis.

Warnings and Precautions
Care must be taken to keep the preparation away from the eyes.

Patients should be advised to avoid:

- smoking whilst applying to the scalp

- fire, flame and heat including use of hair dryer after application

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 *Adverse Reactions*) 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 *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)

- Increasing hydration of the stratum corneum

- Use on thin skin areas

- 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 a few days and reviewed weekly. 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.

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

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.

Effect 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.

Adverse Reactions

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

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

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 Adverse Reactions*).

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.

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 (≥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 ≥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 known

Shelf-life

The expiry date is indicated on the packaging.

Special precaution for storage

Please refer to the outer packaging

Instructions for Use/Handling

Keep container tightly closed when not in use. Contents are flammable. Keep away from fire, flame or heat. Do not leave Dermovate Scalp Application in direct sunlight. Patients should be advised to wash their hands after applying Dermovate.

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Package Leaflet: Information for the user

Dermovate Scalp Application
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 Scalp Application (called 'Dermovate' in this leaflet) 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 scalp problems. These include frequently relapsing dermatoses and psoriasis that have not responded to milder steroid creams, ointments, lotions or scalp applications.

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)
- if you have a skin infection on your scalp
- on a child under 1 year of age.

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 your medicine if:
- you have previously had an allergic reaction with another steroid.
- you are applying the liquid under an airtight dressing. These dressings make it easier for the active ingredient to pass through the skin. It is possible to accidentally end up using too much. Do not bandage or otherwise cover the treated scalp area, unless directed to do so by your doctor.
- If directed to cover the treated area with a dressing, make sure that the skin is cleansed before a fresh dressing is applied to prevent infections.
- you have psoriasis, your doctor will want to see you more often.
- you are applying the liquid to broken, damaged or thin skin.
- you are applying to a large surface area
- you experience blurred vision or other visual disturbances

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

Be very careful not to get the liquid in your eyes.

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 on a child under the age of 1 year.
- Avoid continuous treatment for a long period of time in children over the age of 1 year, as their skin is thinner than adults and as a result may absorb larger amounts.
- Use on children should be limited to a few days and reviewed weekly.
- Dressings or bandages should not be used on children where the scalp application 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 are breast-feeding, think you may become pregnant or are planning to have a baby ask your doctor or pharmacist for advice before taking this medicine

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 put Dermovate on your scalp in the morning and at night. This may be reduced as your scalp problem begins to get better, or stopped when it is better.
- For use on your skin of your scalp only.
- Do not use it more often than prescribed or use it for a long time (such as every day for many weeks or months). If you need treatment for a long time, your doctor may decide you need to use a milder treatment.
- The germs that cause infections like 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.
- Be very careful not to get the liquid in your eyes. Do not touch your eyes until you have washed your hands.
- If you wash or shampoo your hair it should be dried before applying the liquid.
- If you are applying the scalp application on someone else make sure you wash your hands after use or wear disposable plastic gloves.
- **This product is flammable. Keep the liquid away from open fire and flames and all sources of ignition, including smoking, during application and immediately after you've used it.**
- **Do not dry your hair with a hairdryer.**

Guidance on how to apply the liquid
1. Wash your hands.
2. Unscrew the bottle cap and place the nozzle directly on the scalp that needs treating.
3. Gently squeeze the bottle to cover the area with a thin and even layer of liquid.
4. You can rub this liquid in, but you don't have to. Your scalp will feel cool until the liquid has dried.
5. Wash your hands again.
6. Do not exceed the prescribed amount.

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 should not normally last more than a few days, unless your doctor has told you to use it for longer. The doctor may want to see the child every week whilst using Dermovate scalp application.

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 scalp application, 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 scalp problem gets worse, you develop a generalised rash or your skin becomes swollen during treatment. You may be allergic to the scalp application, 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 scalp application is applied.

Uncommon (may affect up to 1 in 100 people)
- skin thinning, this 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 out of the sight and reach of children.
- Do not use this medicine after the expiry date which is stated on the bottle label or carton after (EXP).
- Store as directed on the outer package
- Keep the container tightly closed when not in use. Contents are flammable. Keep away from all sources of fire, flame and heat. Do not leave in direct sunlight.
- 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 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 carbomer, isopropyl alcohol, sodium hydroxide and purified water

What Dermovate looks like and contents of the pack
Within each carton is a specially designed plastic bottle with a nozzle and cap that contains sticky liquid.

More Information
If you have any questions or are not sure about anything, ask your doctor or pharmacist who will advise you.

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包裝單張：使用者須知

特美膚 (Dermovate) 頭皮水
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)頭皮水（本單張中名為‘特美膚’）含有一種名為 clobetasol propionate 的藥物。它屬於一種稱為類固醇的藥物。減輕皮膚刺激並且消腫。

特美膚(Dermovate)被用於減輕某些因頭皮問題而引起的發紅和痕癢。這包括一些對藥 效溫和的類固醇乳膏、軟膏、乳霜或頭皮水有耐受性並經常復發的皮膚病和銀屑病（psoriasis）。

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 或本藥物中任何其他成份（在第 6 部分列出）過敏。
- 如果您的頭皮上有皮膚感染。
- 未滿 1 歲的兒童。

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

如果您存在如下情況，請在用藥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。
- 您在有不透氣的敷料遮蓋的情況下使用本頭皮水。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。有可能會意外地吸收過多藥物。除非有醫生指示，否則請勿在頭皮上的治療區域纏繞繃帶或用其他方式遮蓋。

- 如果醫生指示要用敷料遮蓋治療區域，請確保在蓋上新敷料前清潔皮膚，以防感染。
- 您患有銀屑病（psoriasis），您的醫生將會希望您能多覆診。
- 您在破皮、受損或較薄的皮膚處使用頭皮水。
- 您將在較大的範圍塗抹頭皮水。
- 出現視野模糊或其他視覺障礙的情況。

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。 務必小心謹慎，切勿讓頭皮水進入眼睛。 如果您無法確定上述任何情況是否適用於您，請在服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 1 歲以上的兒童，要避免長期使用本藥物對其進行持續治療，因為他們的皮膚厚度比成年人薄，會因此吸收更多的藥物。
- 如對兒童施予本藥物，最多只可用藥數天並需要每周進行檢查。
- 如對兒童施予本藥物，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。

3. 如何使用特美膚(Dermovate)

務必遵從醫生指示服用。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，您會在早上和晚間在頭皮部位用藥。隨著頭皮情況有所好轉，用藥量可適當減少或在好轉後停止用藥。
- 僅可用於頭皮上。
- 用藥次數不得超過處方規定，不得長期使用本藥物（例如每天使用，連續用藥數周或數月）。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治療方法。
- 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。
- 務必小心謹慎，切勿讓頭皮水進入眼睛。如果沒有洗手，切勿用手觸碰眼睛。
- 如果您用水或洗髮水洗頭，那麼在使用本藥物前應先擦乾頭髮。
- 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。
- **本藥物易燃。在用藥期間以及用藥完成後，立即讓本頭皮水遠離明火和火焰以及所有**

點火源頭，包括燃點香煙。

- **請勿用吹風機吹乾頭髮。**

用藥指南

1 清洗雙手。
2 擰開瓶蓋，將瓶嘴直接對準需要用藥的頭皮區域。
3 輕輕擠壓瓶身，讓頭皮水均勻及薄薄地覆蓋這一區域。
4 您可以輕揉頭皮以促進頭皮水吸收，但這不是必需的。在頭皮水乾透之前，您的頭皮會有涼爽的感覺。
5 再次清洗雙手。
6 用藥量不得超過處方規定。

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。
- 除非醫生告知用藥會持續更長時間，否則兒童的療程一般不要超過數天。在使用特美膚(Dermovate)頭皮水期間，您的孩子可能要每周就醫，接受檢查。

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) 如果您忘記使用頭皮水，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：**

- 發現頭皮問題惡化，出現周身皮疹或在治療期間皮膚腫脹。您可能對本頭皮水過敏，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
- 病情惡化
- 用藥處有刺激感/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：
- 體重增加緩慢
- 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進行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。

- 如果本藥物放置超過了藥瓶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。
- 不使用時，請保持容器密封。容器盛有易燃物品。讓本藥物遠離所有明火、火焰和熱量來源。切勿將藥物置於陽光直射的環境中。
- 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)含有哪些

成份

- 活性成分為 clobetasol propionate。每 1 克藥物還有 0.5 毫克 clobetasol propionate (0.05% w/w)。
- 其他成為有 carbomer、isopropyl alcohol、sodium hydroxide 和 purified water。

特美膚(Dermovate)的外觀和包裝內容

每個包裝盒內有一個特別設計的、帶有瓶嘴和瓶蓋的塑膠瓶，其中裝有粘性藥液。

更多諮詢 如果您有任何疑問或有不明白的地方，請諮詢您的醫生或藥劑師，他們會給您建議。

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