Betnovate Cream and Ointment

1. Name of the Medicinal Product
Betnovate Cream and Ointment

2. Qualitative and Quantitative Composition
Betamethasone Valerate 0.122% W/W

Excipients with known effect (For Betnovate Cream only):
Chlorocresol
Cetostearyl alcohol

For the full list of excipients, see section 6.1

3. Pharmaceutical Form
Aqueous Cream and Ointment

4. Clinical Particulars

4.1 Therapeutic indications
Betnovate is a potent topical corticosteroid indicated for adults, elderly and children over 1 year for the relief of the inflammatory and pruritic manifestations of steroid responsive dermatoses. These include the following:

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

4.2 Posology and method of administration
Route of administration: Cutaneous

Betnovate Cream is especially appropriate for moist or weeping surfaces.
Betnovate Ointment is especially appropriate for dry, lichenified or scaly lesions

Apply thinly and gently rub in using only enough to cover the entire affected area once or twice daily for up to 4 weeks until improvement occurs, then reduce the frequency of application or change the treatment to a less potent preparation.
Allow adequate time for absorption after each application before applying an emollient.

In the more resistant lesions, such as the thickened plaques of psoriasis on elbows and knees, the effect of betamethasone valerate 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 in such lesions; thereafter, improvement can usually be maintained by regular application without occlusion.

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

Therapy with betamethasone valerate 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 betamethasone valerate.

Recalcitrant dermatoses

Patients who frequently relapse
Once an acute episode has been treated effectively with a continuous course of topical corticosteroid, intermittent dosing (apply once a day twice a week 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
Betamethasone valerate 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; therefore, courses should be limited to five days and occlusion should not be used.

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

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

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

4.3 Contra-indications
Hypersensitivity to the active substance or any of the excipients in the excipients listed in section 6.1.

The following conditions should not be treated with Betnovate:

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

Betnovate is contraindicated in dermatoses in infants under one year of age, including dermatitis.

4.4 Special warnings and precautions for use

Betnovate should be used with caution in patients with a history of local hypersensitivity to other corticosteroids. Local hypersensitivity reactions (see section 4.8) 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 4.8*).*

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 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.

Paediatric population

In infants and children under 12 years of age, treatment courses should be limited to five days and occlusion should not be used; long-term continuous topical corticosteroid therapy should be avoided where possible, as adrenal suppression can occur.

Infection risk with occlusion

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

Use in Psoriasis

Topical 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.

Application to the face
Prolonged application to the face is undesirable as this area is more susceptible to atrophic changes; therefore, treatment courses should be limited to five days and occlusion should not be used.

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.

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.

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

4.5 Interaction with other medicaments and other forms of interaction
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.

4.6 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 Betnovate in pregnant women.

Topical administration of corticosteroids to pregnant animals can cause abnormalities of foetal development (see section 5.3).

The relevance of this finding to humans has not been established; however, administration of Betnovate 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 topical administration of corticosteroids could result in sufficient systemic absorption to produce detectable amounts in breast milk. Administration of Betnovate during lactation should only be considered if the expected benefit to the mother outweighs the risk to the infant.

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

4.7 Effect on ability to drive and use machines
There have been no studies to investigate the effect of Betnovate 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 Betnovate.

4.8 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, alopecia, trichorrhexis

Skin and Subcutaneous Tissue Disorders

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

General Disorders and Administration Site Conditions

Very rare	Application site irritation/pain

**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 4.4)

4.9 Overdosage

Symptoms and signs

Topically applied Betnovate 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 4.8).

Treatment

In the event of overdose, Betnovate 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.

5. Pharmacological properties

5.1 Pharmacodynamic properties

ATC code

D07AC Corticosteroids, potent (group III)

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.

5.2 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 because 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.

5.3 Preclinical safety data

Reproductive toxicity
Subcutaneous administration of Betnovate to mice or rats at doses ≥0.1 mg/kg/day or rabbits at doses ≥12 micrograms/kg/day during pregnancy produced foetal abnormalities including cleft palate and intrauterine growth retardation.

The effect on fertility of Betnovate has not been evaluated in animals.

6. Pharmaceutical Particulars

6.1 List of excipients

Betnovate Cream: Chlorocresol, Cetomacrogol 1000, Cetostearyl Alcohol, White Soft Paraffin, Liquid Paraffin, Sodium dihydrogen phosphate dihydrate, Phosphoric Acid, Sodium Hydroxide, Purified Water

Betnovate Ointment: Liquid Paraffin, White Soft Paraffin

6.2 Incompatibilities
None known.

6.3 Shelf-life
The expiry date is indicated on the packaging.

6.4 Special precautions for storage
Please refer to the outer packaging.

Version: HK092021 (GDS10/UKSPC20210210)

Package Leaflet: Information for the User

Betnovate Cream and Ointment
betamethasone valerate

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 Betnovate is and what it is used for

Betnovate contains a medicine called betamethasone valerate. It belongs to a group of medicines called steroids that reduce swelling and irritation.

Betnovate is used to help reduce the redness and itchiness of certain skin problems, such as eczema, psoriasis and dermatitis.

2. What you need to know before you use Betnovate

Do not use Betnovate:

- if you are allergic (hypersensitive) to betamethasone valerate or any of the other ingredients of Betnovate (listed in section 6)
- on a child under 1 year old
- 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 back passage or private parts
    - infected skin (unless the infection is being treated with an anti-infective medicine at the same time)
    - 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 Betnovate.

Warnings and precautions

Talk to your doctor or pharmacist before using Betnovate 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.
- you have psoriasis, your doctor will want to see you more often.
- using for a chronic leg ulcer as you may be at increased risk of local allergic reaction or infection.
- you are applying to a large surface area
- you are applying the cream/ointment 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/ointment repeatedly enters the eye.
- you have an infection of the skin as this will need to be treated
- you are applying to thin skin such as the face or on children as their skin is thinner than adults and as a result may absorb larger amounts.
- Dressing or bandages should not be used on children or on the face where the cream/ointment is applied.
- Use on children or on the face should be limited to 5 days

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

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.

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 Betnovate

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 and breast-feeding and fertility

If you are pregnant or are 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.

Betnovate Cream contains chloroscresol and cetostearyl alcohol

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

3. How to use Betnovate

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 Betnovate once or twice a day. This may be reduced as your skin begins to get better.
- This cream/ointment is for use on your skin only.
- Do not use more than the amount prescribed for you.
- 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.
- The germs that cause infections like warm, moist conditions under bandages or dressings so always clean the skin before a fresh dressing is put on.
- If you are applying the cream/ointment on someone else make sure you wash your hands after use or wear disposable plastic gloves.
- If your skin problem does not improve in 2 to 4 weeks, talk to your doctor.

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 Betnovate 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

Number of fingertip units needed					
Child's age	**Face and neck**	**Arm and hand**	**Leg and foot**	**Front**	**Back including buttocks**
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 it 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 5 days - unless your doctor has told you to use it for longer.

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 Betnovate to your face
You should only apply the cream/ointment to your face if your doctor tells you to. It should not be used for more than 5 days, as the skin on your face thins easily. **Do not let the cream/ointment get into your eyes.**

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

If you forget to use Betnovate
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.

If you stop using Betnovate
If you use Betnovate 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 Betnovate 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 Betnovate, have an infection or need other treatment.
- you have psoriasis and get raised bumps with pus under the skin. This can happen very rarely during or after treatment and is known as pustular psoriasis.

Other side effects you may notice when using Betnovate include:

Common: may affect up to 1 in 10 people

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

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

- an increased risk of infection
- an allergic skin reaction where the cream/ointment is applied
- rash, itchy bumpy skin or redness of the skin
- thinning and dryness of your skin and it may also damage or wrinkle more easily
- stretch marks may develop
- blood vessels under the surface of your skin may become more noticeable
- an increase or reduction in hair growth or hair loss and changes in skin colour
- 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)
- a decrease in the level of the hormone cortisol in your blood
- increased blood sugar levels or sugar in the urine
- high blood pressure

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 Betnovate

- 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 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 Betnovate cream contains

- The active ingredient is betamethasone valerate. Each 1 g contains 1 mg of betamethasone (0.1% w/w) as valerate.
- The other ingredients are chlorocresol, cetomacrogol 1000, cetostearyl alcohol, white soft paraffin, liquid paraffin, sodium dihydrogen phosphate dihydrate, phosphoric acid, sodium hydroxide and purified water.

What Betnovate ointment contains

- The active ingredient is betamethasone valerate. Each 1 g contains 1 mg of betamethasone (0.1% w/w) as valerate.
- The other ingredients are liquid paraffin and white soft paraffin.

What Betnovate 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

裨乃膚 (Betnovate)乳膏及油膏
betamethasone valerate

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. 裨乃膚 (Betnovate)是什麼及有何用途
裨乃膚 (Betnovate)含有一種被稱為betamethasone valerate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。

裨乃膚 (Betnovate)被用於減輕某些皮膚問題引起的發紅和痕癢的狀況，例如濕疹，銀屑病和皮膚炎。

2. 在使用裨乃膚 (Betnovate)前，您需要了解哪些資訊
如有以下情況，切勿使用裨乃膚 (Betnovate)：
- 如果您對betamethasone valerate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

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，請在使用裨乃膚 (Betnovate)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，請在使用裨乃膚 (Betnovate)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。
- 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。
- 在較大的皮膚面積上使用本乳膏/油膏。
- 在皮膚破損處或皮膚褶皺下使用本乳膏/油膏。
- 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。
- 您有皮膚感染，因為你需要接受治療。
- 在兒童身上或皮膚較薄處，例如面部，使用本藥物，因為兒童的皮膚屏障較成人薄，容易吸收過多份量
- 如果在兒童身上或面部使用本藥物，切勿用敷料或繃帶遮住用藥部位。
- 如果要在兒童身上或面部用藥，療程應限制在5天以內。

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。

由於嚴重燒傷的風險，切勿吸煙或接近火種。布料，包括衣物、床上用品、敷料等與本藥物接觸會更易燃燒和會是嚴重的火警風險物。清洗衣物及床上用品可能會降低本藥物的積聚但不能完全除去。
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。

其他藥物與裨乃膚 (Betnovate)

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。

裨乃膚 (Betnovate)乳膏中含有 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）

3. 如何使用裨乃膚 (Betnovate)

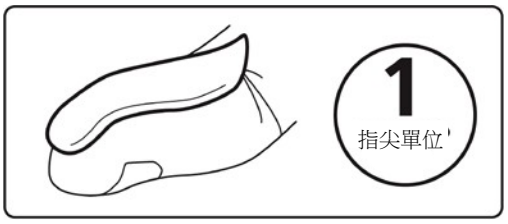
請始終嚴格按照醫生指示用藥。如果您有不明白的地方，請諮詢您的醫生或藥劑師。

使用本藥物

- 一般情況下，每天使用1至2次。隨著皮膚情況有所好轉，用藥量可適當減少
- 該乳膏/油膏只可外用於皮膚上。
- 切勿使用多於處方的份量。
- 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）。
- 造成感染的細菌喜歡敷料下溫暖、潮濕的環境。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。
- 如果您的皮膚問題在用藥2-4周內都沒有改善，請諮詢您的醫生。

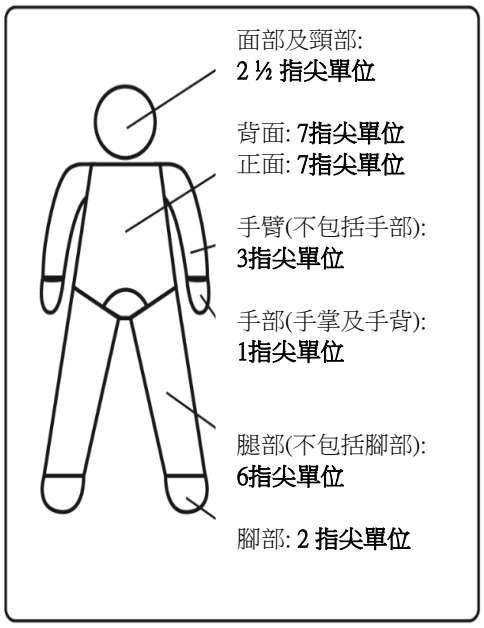
用藥指南

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

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
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

- 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得超過5天。

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。

如果您要將裨乃膚 (Betnovate)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。**切勿讓本乳膏/油膏進入眼睛。**

如果您使用了過量的裨乃膚 (Betnovate)
如果您使用了過量的裨乃膚 (Betnovate)，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。

如果您忘記使用裨乃膚 (Betnovate)
如果您忘記使用裨乃膚 (Betnovate)，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。

如果您停止使用裨乃膚 (Betnovate)
如果您一直在按時使用裨乃膚 (Betnovate)，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
雖然並不是每一個人使用此藥物也會出現副作用，但正如使用其他藥物一樣，使用此藥物也有可能出現副作用。

如果出現以下情況，請停止使用裨乃膚 (Betnovate)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。這種非常罕見的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）。

您在使用裨乃膚 (Betnovate)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。

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
- 皮疹，皮膚痕癢腫脹，發紅
- 皮膚變薄或乾燥，而且可能更容易受損或起皺
- 皮膚可能會出現伸展紋
- 皮下血管會變得更加清晰可見

- 增加或減少頭髮生長，脫髮和膚色改變
- 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）
- 血液中的皮質醇下降
- 血糖或尿糖升高
- 高血壓

未知（根據現有數據未能估計副作用出現頻率）

- 視力模糊

5. 如何存放裨乃膚 (Betnovate)

- 請將本藥物放在兒童無法看見並觸及的地方。
- 如果裨乃膚 (Betnovate)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

裨乃膚(Betnovate) 乳膏含有哪些成份

- 活性成分為 betamethasone valerate。每 1 克乳膏含有 1 毫克 betamethasone (0.1% w/w) as valerate。
- 其他成分有 chlorocresol、cetomacrogol 1000、cetostearyl alcohol、white soft paraffin、liquid paraffin、sodium dihydrogen phosphate dihydrate 、phosphoric acid 、sodium hydroxide 和 purified water。

裨乃膚(Betnovate) 油膏含有哪些成份

- 活性成分為 betamethasone valerate。每 1 克油膏含有 1 毫克 betamethasone (0.1% w/w) as valerate。
- 其他成分有 liquid paraffin 和 white soft paraffin。

裨乃膚(Betnovate)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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