

# DATA SHEET

## BETNOVATE™ LOTION

### *Name of each active ingredient*

Betamethasone Valerate BP 0.122% w/w

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### **Presentation**

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BETNOVATE Lotion, a white, translucent, aqueous fluid, contains 0.122% w/w betamethasone valerate.

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### **Indications**

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BETNOVATE Lotion 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
  - Insect bite reactions
  - Miliaria (prickly heat); and
  - Adjunct to systemic steroid therapy in generalised erythroderma.
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### **Dosage and Administration**

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

BETNOVATE Lotion is especially appropriate for treatment of hairy areas or when a minimal application to a large area is required.

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 the elbows and knees, the effect of BETNOVATE Lotion 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.

Due to the flammable nature of BETNOVATE Lotion, patients should avoid smoking or being near an open flame during application and immediately after use.

### ***Atopic dermatitis (eczema)***

Therapy with BETNOVATE Lotion 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 BETNOVATE Lotion.

### **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 regime 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.

#### ***Children aged 1 year and over***

BETNOVATE Lotion is contraindicated in children under one year of age (see Contraindications).

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 BETNOVATE Lotion 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.

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## Contraindications

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The following conditions should not be treated with BETNOVATE Lotion:

- Untreated cutaneous infections
- Rosacea
- Acne vulgaris
- Pruritus without inflammation
- Perianal and genital pruritus
- Hypersensitivity to the preparations.
- Perioral dermatitis

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

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## Warnings and Precautions

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### ***Hypersensitivity***

BETNOVATE should not be used in patients with a history of local hypersensitivity to corticosteroids or to any of the excipients in the preparation. Local hypersensitivity reactions (see Adverse Effects) may resemble symptoms of the condition under treatment.

### ***Reversible hypothalamic-pituitary-adrenal (HPA) axis suppression***

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 Adverse Effects).

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.

### ***Use in children***

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.

### ***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.

### ***Application to the eyelids***

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

### ***Concomitant infection***

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

### ***Chronic leg ulcers***

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

### ***Fertility***

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

### ***Use in pregnancy***

There are limited data from the use of betamethasone valerate in pregnant women.

Topical administration of corticosteroids to pregnant animals can cause abnormalities of foetal development.

The relevance of this finding to humans has not been established; however, administration of BETNOVATE Lotion 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.

### ***Use in 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 Lotion during lactation should only be considered if the expected benefit to the mother outweighs the risk to the infant.

If used during lactation BETNOVATE Lotion should not be applied to the beasts to avoid accidental ingestion by the infant.

### ***Effects on ability to drive and use machines***

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

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## **Adverse Effects**

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Adverse drug reactions 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 ( $\geq 1/1000$  and  $< 1/100$ ), rare ( $\geq 1/10,000$  and  $< 1/1000$ ) and very rare ( $< 1/10,000$ ) including isolated reports.

### ***Post-marketing data***

#### **Infections and Infestations**

Very rare: Opportunistic infection

#### **Immune system disorders**

Very rare: Local hypersensitivity

#### **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 HPA axis suppression.

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## **Interactions**

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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.

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## **Overdose**

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### ***Symptoms and Signs***

Topically applied betamethasone valerate may be absorbed in sufficient amounts to produce systemic effects. Acute overdosage is unlikely to occur, however, in the case of chronic overdosage or misuse, the features of hypercortisolism may occur (see Adverse Effects).

### ***Treatment***

In the event of overdose, BETNOVATE Lotion 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 or as recommended by the National Poisons Centre (0800 764 766).

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## **Further Information**

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The least potent corticosteroid which will control the disease should be selected.

### ***Actions***

Betamethasone valerate is an active topical corticosteroid which produces a rapid response in those inflammatory dermatoses that are normally responsive to topical

corticosteroid therapy, and is often effective in the less responsive conditions such as psoriasis.

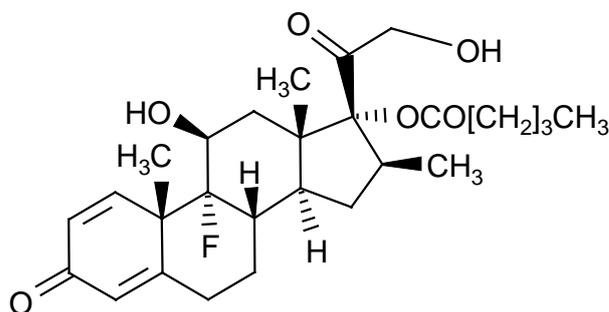
### **Pharmacokinetics**

As with other topical corticosteroids, sufficient betamethasone valerate may be absorbed to give systemic effects if applied under an occlusive dressing or when the skin is broken.

### **Other**

#### **Chemical Structure**

Betamethasone valerate



#### **List of excipients**

BETNOVATE Lotion also contains:

- methyl hydroxybenzoate
- xanthan gum
- cetostearyl alcohol
- liquid paraffin
- isopropyl alcohol
- glycerol
- cetomacrogol 1000
- sodium citrate
- citric acid monohydrate
- purified water

BETNOVATE Lotion does not contain lanolin.

BETNOVATE Lotion contains parabens.

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## **Pharmaceutical Precautions**

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### **Instructions for Handling**

There are no special requirements for handling of this product.

### **Incompatibilities**

No incompatibilities have been identified.

### ***Special Precautions for Storage***

Store below 25°C, out of direct sunlight.

Keep container tightly closed when not in use. Contents are flammable. Keep away from fire, flame or heat.

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### **Package Quantities**

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BETNOVATE Lotion is supplied in 50 mL bottles.

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### **Medicine Schedule**

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Prescription Medicine

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### **Sponsor Details**

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### **Date of Preparation**

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BETNOVATE™ is a trade mark of the GlaxoSmithKline group of companies.