

# DATA SHEET

## BETNOVATE®

### *Betamethasone Valerate 0.122% w/w Lotion BP*

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## Presentation

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BETNOVATE Lotion, a white, translucent, aqueous fluid, contains 0.122% w/w betamethasone 17-valerate.

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## Uses

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### **Actions**

Betamethasone-17-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-17-valerate may be absorbed to give systemic effects if applied under an occlusive dressing or when the skin is broken.

### **Therapeutic Indications**

BETNOVATE Lotion is a potent topical corticosteroid indicated 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.

### **Dosage and Administration**

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 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.

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

Therapy with BETNOVATE 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.

### **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.

### **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**

The following conditions should not be treated with BETNOVATE:

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

### **Warnings and Precautions**

BETNOVATE should be used with caution 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.

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

**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.

***Use During 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 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 betamethasone valerate 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.

**Effects on Ability to Drive and Operate Machinery**

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 effects profile of BETNOVATE.

### **Adverse Effects**

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 hypothalamic-pituitary adrenal (HPA) axis suppression.

### **Interaction with Other Medicinal Products 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.

### **Overdose**

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). 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 or as recommended by the national poisons centre, where available.

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## **Pharmaceutical particulars**

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### **Pharmaceutical Precautions**

Store below 25°C, out of direct sunlight.

### **Packaging Quantities**

BETNOVATE Lotion is supplied in 50mL bottles.

### **Further Information**

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

### **Excipients**

BETNOVATE Lotion also contains methyl hydroxybenzoate, xanthan gum, cetostearyl alcohol, liquid paraffin, isopropyl alcohol, glycerol, cetomacrogol 1000, sodium citrate, citric acid monohydrate and purified water.

BETNOVATE Lotion does not contain lanolin.

BETNOVATE Lotion contains parabens.

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## **Medicines classification**

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Prescription Medicine

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## **Name and address**

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GlaxoSmithKline NZ Limited  
AMP Centre  
Cnr Albert & Customs Streets  
Private Bag 106600  
Downtown Auckland  
NEW ZEALAND

Phone: (09) 367 2900

Facsimile: (09) 367 2506

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## **Date of preparation**

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