

## Data Sheet

# Skincalm

*Hydrocortisone 1% w/w*

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## Presentation

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A white, smooth cream with the odour of chlorocresol.

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## Uses

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### *Actions*

When applied topically hydrocortisone acetate is primarily effective because of its anti-inflammatory, anti-pruritic and vasoconstrictive actions.

### *Pharmacokinetics*

Hydrocortisone is absorbed through the skin, particularly in denuded areas. Hydrocortisone is metabolised in the liver and most body tissues to hydrogenated and degraded forms such as tetrahydrocortisone and tetrahydrocortisol. These are excreted in the urine, mainly conjugated as glucuronides, together with a very small proportion of unchanged hydrocortisone.

When administered by topical application, particularly under an occlusive dressing or when the skin is broken, sufficient corticosteroid may be absorbed to give systemic effects.

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## Indications

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For contact dermatitis from allergies or irritants and for skin reactions to insect bites.

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## Dosage and Administration

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Use sparingly on a small area, once or twice a day, for a maximum of 7 days.

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## Contraindications

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Skin lesions caused by infection with viruses (eg herpes, chickenpox), perioral dermatitis, rosacea, fungal skin infections (eg candidiasis, tinea) and ulcerative conditions. Hypersensitivity to any of the ingredients.

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## **Warnings and Precautions**

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Should hypersensitivity occur, application should be stopped immediately. This preparation is not to be used in the eye, as there is a potential risk of glaucoma and cataract.

Co-existing infection may require specific antibiotics or withdrawal of therapy.

Babies and children up to four years should not be treated with dermal steroids for longer than three weeks. In infants the napkin may act as an occlusive dressing and increase absorption. Adrenal suppression is more likely to occur in infants and children. Do not use in children under 2 years of age without medical advice.

Systemic absorption resulting in adrenal suppression may occur especially under occlusion with weekly doses of over 50 g, 30 g and 15 g of respectively mild to moderate, potent and very potent corticosteroids. Routine steroid precautions must be observed if the patient is stressed, then, following such use eg as in surgery.

Prolonged use on flexures and intertriginous areas is undesirable.

Do not use on the face, anal or genital areas or on broken or infected skin, eg impetigo, cold sores, acne, or athlete's foot.

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## **Use in Pregnancy**

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Dermal steroids should not be used in large amounts or for prolonged periods of time in pregnancy - foetal abnormalities have been seen in animals due to systemic absorption. Do not use in pregnancy without medical advice.

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## **Adverse Effects**

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Adverse effects associated with topical low-strength hydrocortisone products are highly unlikely. Significant abuse of the product will be required to cause adverse effects. The adverse effects that potentially could occur under this circumstance are divided into topical and systemic. Topical: Cutaneous atrophy, petechiae, steroid acne. Systemic: These occur when relatively large amounts of hydrocortisone are absorbed from the skin. The amount used, the duration of use and the nature of the skin influences absorption. The most likely situation for this to occur is with the use of high potency corticosteroids in infants with nappy rash.

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## Interactions

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Not applicable

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## Overdosage

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Symptoms: Excessive prolonged use of topical corticosteroids can suppress pituitary-adrenal function resulting in secondary adrenal insufficiency.

Treatment: Appropriate symptomatic treatment is indicated. Acute hypercorticoid symptoms are virtually reversible. Treat electrolyte imbalance, if necessary. In cases of chronic toxicity, slow withdrawal of corticosteroids is advised.

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## Pharmaceutical Precautions

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Store below 25°C.

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## Medicine Classification

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Restricted Medicine.

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## Package Quantities

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Tubes of 30 g.

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## Further Information

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Skincalm Cream 1% does not contain lanolin or parabens.

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## Name and Address

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## **Date of Preparation**

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4 June 2010