Calcipotriol Ointment 0.005% w/w



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Composition:

Each gram contains Anhydrous Calcipotriol BP 0.005% w/w In Neutral Ointment base g.s

DESCRIPTION

A synthetic vitamin D3 derivative, for topical dermatological use.

MECHANISM OF ACTION

([°]CALPSOR[™]

Calcipotriol, a synthetic analog of vitamin D3, is similar to the natural 1,25-(OH)2-D3 (Calcitriol) occurring in the human body. Calcipotriol (i.e., active vitamin D3) is the metabolite of cholecalciferol (i.e., inactive vitamin D3). Calcipotriol binds to vitamin D receptors on epidermal cells and tissue cells. Activation of this ligand-receptor complex results in inhibition of proliferation of keratinocytes and induction of cell differentiation in psoriaticskin.

INDICATION

Psoriasis vulgaris.

DOSAGE AND ADMINISTRATION

Calcipotriol ointment should be applied sparingly to the affected skin lesions twice daily. For some patients the maintenance therapy may be achieved with less frequent application. The weekly dose should not exceed 100 qm ointment.

CONTRAINDICATIONS

Calcipotriol is contraindicated in those patients with a history of hypersensitivity to any of the components of the preparation. It should not be used by patients with demonstrated hypercalcemia or evidence of vitamin D toxicity. Calcipotriol should not be used on the face.

PRECAUTIONS

- General
- 1. Always wash hands thoroughly after use.
- Use of Calcipotriol may cause irritation of lesions and surrounding uninvolved skin. If irritation develops, Calcipotriol should be discontinued.
- Transient, rapidly reversible elevation of serum calcium has occurred with use of Calcipotriol. If elevation in serum calcium outside the normal range occurs, discontinue treatment until normal calcium levels are restored.

Pregnancy and Lactation

There are no adequate and well-controlled studies in pregnant women. Therefore, Calcipotriol ointment should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Pediatric Use

Safety and effectiveness of Calcipotriol in pediatric patients have not been established. Because of a higher ratio of skin surface area to body mass, pediatric patients are at greater risk than adults of systemic adverse effects when they are treated with topical medication.

ADVERSE REACTIONS

In controlled clinical trials with Calcipotriol, the most frequent adverse reactions reported were burning, itching and skin irritation. Other less commonly reported adverse reactions are erythema, dry skin, peeling, rash, dermatitis, skin atrophy, hyperpigmentation, hypercalcemia and folliculitis.

OVERDOSAGE

Excessive use (more than 100 g weekly) may cause elevated serum calcium, which rapidly subsides when the treatment is discontinued.

STORAGE

Store at a temperature not exceeding 25°C, away from light and moisture. Do not refrigerate or freeze. Keep out of reach of children.

PRESENTATION

CALPSOR[™] is available in 30g aluminum tube with screw cap.

For further details, please contact: **Biocon Limited** 20th KM, Hosur Road, Electronics City, Bangalore - 560 100. India

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Marketed by: Biocon Limited, 20th KM, Hosur Road, Electronics City, Bangalore - 560 100.

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To report adverse events and/or product complaints visit our website **www.biocon.com** or call toll free No: **1800 102 9465** or e mail us at **drugsafety@biocon.com**.

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