



Only for the use of a Registered Medical Practitioner or a Hospital or a Laboratory.

Rx

# Calcipotriol 0.005% w/v and Clobetasol Propionate 0.05% w/v Solution



**CALPSOR<sup>®</sup> C Lotion**

कैल्प्सोर सी लोशन

## COMPOSITION:

Each mL contains  
Calcipotriol Monohydrate BP 50 mcg  
Equivalent to Calcipotriol (anhydrous) 500 mcg  
Clobetasol Propionate IP q.s.  
In base

## PHARMACEUTICAL FORM

Topical solution

**ATC Code:** D05AX52

## DESCRIPTION

Calcipotriol a synthetic vitamin D3 derivative and Clobetasol Propionate a corticosteroid, for topical dermatological use.

## MECHANISM OF ACTION

Calcipotriol, a synthetic analog of vitamin D3, is similar to the natural 1,25-(OH)<sub>2</sub>-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 psoriatic skin.

Clobetasol Propionate, a corticosteroid has anti-inflammatory, antipruritic, and vasoconstrictive properties. The mechanism of the anti-inflammatory activity is generally unclear. However, corticosteroids are thought to induce phospholipase A2 inhibitor proteins, preventing arachidonic acid release and the biosynthesis of potent mediators of inflammation.

## INDICATION

Topical Calcipotriol and Clobetasol Propionate is indicated for the topical treatment of plaque psoriasis.

## DOSAGE AND ADMINISTRATION

Topical Calcipotriol and Clobetasol Propionate solution to be applied to the lesions in hairy areas on the body or scalp once daily for upto 4 weeks. It should not be applied on the face.

## CONTRAINDICATIONS

Calcipotriol and Clobetasol Propionate 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 and Clobetasol Propionate should not be used on the face.

Due to the content of corticosteroid, it is contraindicated in the following conditions: Viral (e.g. herpes or varicella) lesions of the skin, fungal or bacterial skin infections, parasitic infections, skin manifestations in relation to tuberculosis or syphilis, rosacea, perioral dermatitis, acne vulgaris, atrophic skin, striae atrophicae, fragility of skin veins, ichthyosis, acne rosacea, ulcers, wounds, perianal and genital pruritus. It is contraindicated in guttate, erythrodermic, exfoliative and pustular psoriasis. It is also contraindicated in patients with severe renal insufficiency or severe hepatic disorders.

## PRECAUTIONS

### General

- 1) Avoid contact with the eyes or mucous membranes. Discontinue use of Calcipotriol and Clobetasol Propionate if a sensitivity reaction occurs or if excessive irritation develops on uninvolved skin areas.
- 2) Use of Calcipotriol and Clobetasol Propionate may cause transient irritation of both lesions and surrounding uninvolved skin. If irritation develops, discontinue its use.
- 3) Always wash hands thoroughly after use to avoid inadvertent transfer to other body areas, especially the face.
- 4) Reversible elevation of serum calcium has occurred with use of topical Calcipotriol. If elevation in serum calcium outside the normal range should occur, discontinue treatment until normal calcium levels are restored.

## Pregnancy and Lactation

There are no adequate and well-controlled studies in pregnant women. Therefore, it should be used during pregnancy unless the potential benefit justifies the potential risk to the fetus. Because many drugs are excreted in human milk, caution should be exercised when Calcipotriol and Clobetasol Propionate applied to a nursing women.

## Pediatric Use

There is no clinical trial experience in children. Children may demonstrate greater susceptibility to systemic steroid related adverse effects due to a larger skin surface area to body weight ratio as compared to adults.

## ADVERSE REACTIONS

In clinical trials, the most common adverse reaction associated with Calcipotriol was pruritus. Pruritus was usually mild and no patients were withdrawn from treatment.

Calcipotriol is associated with local reactions such as transient lesional and perilesional irritation. Rare cases of hypersensitivity reaction have been reported. Hypercalcemia can develop but is usually related to excessive administration.

Topical corticosteroids can cause the same spectrum of adverse effects associated with systemic steroid administration, including adrenal suppression. Adverse effects associated with topical corticosteroids are generally local and include dryness, itching, burning, local irritation, striae, atrophy of the skin or subcutaneous tissues, telangiectasia, hypertrichosis, folliculitis, skin hypopigmentation, allergic contact dermatitis, maceration of the skin, miliaria, or secondary infection. If applied to the face, acne rosacea or perioral dermatitis can occur. In addition, there are reports of the development of pustular psoriasis from chronic plaque psoriasis following reduction or discontinuation of potent topical corticosteroid products.

## OVERDOSAGE

Excessive use of Calcipotriol and Clobetasol Propionate may cause elevation of serum calcium, discontinue the treatment until normal calcium levels are restored.

## Information for Patients

Patients using Calcipotriol and Clobetasol Propionate solution should receive the following information and instructions:

- 1) This medication is to be used only as directed by the physician. It is for external use only. Avoid contact with the face or eyes. As with any topical medication, patients should wash their hands after application.
- 2) This medication should not be used for any disorder other than that for which it was prescribed.
- 3) Patients should report to their physician any signs of adverse reactions.
- 4) Patients that apply Calcipotriol and Clobetasol Propionate to exposed portions of the body should avoid excessive exposure to either natural or artificial sunlight (including tanning booths, sun lamps, etc).

**Shelf Life :** Please refer to Carton/Label

## STORAGE:

**Store at a temperature not exceeding 30°C, Protect from light. Do not freeze.**

For dermatologic use only. Not for ophthalmic use.

Flammable. Keep the solution away from fire or flame.

Close the flip top cap tightly after use.

Keep out of reach of children.

## PRESENTATION

**CALPSOR<sup>®</sup> C Lotion** is available in 20 mL HDPE white flat bottle with HDPE flip top cap.

Marketed by:

**Biocon Biologics India Limited**  
Biocon House, Semicon Park,  
Electronics City, Phase - II,  
Bengaluru - 560 100, India.

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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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