



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

Calcipotriol Solution 0.005%w/v



CALPSOR[®] *Lotion*

कैल्पसोर लोशन

COMPOSITION:

Each ml contains:

Calcipotriol Monohydrate BP
equivalent to Calcipotriol (anhydrous) 50 mcg
In base q.s.

PHARMACEUTICAL FORM

Topical solution

ATC Code: D05AX02

DESCRIPTION

CALPSOR[®] Lotion is a synthetic vitamin D3 derivative, for topical dermatological use.

MECHANISM OF ACTION

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 psoriatic skin.

INDICATION

Topical calcipotriol is indicated for the topical treatment of plaque psoriasis.

DOSAGE AND ADMINISTRATION

Calcipotriol solution to be applied to the lesions in hairy areas on the body or scalp twice daily. Calcipotriol solution should not be applied on the face.

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) Avoid contact with the eyes or mucous membranes. Discontinue use of Calcipotriol if a sensitivity reaction occurs or if excessive irritation develops on uninvolved skin areas.
- 2) Use of Calcipotriol 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 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, Calcipotriol should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. It is not known whether it is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when Calcipotriol is administered to a nursing woman.

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 of Calcipotriol may elevate serum calcium, discontinue the treatment until serum calcium levels are within normal limits.

Information for Patients

Patients using Calcipotriol 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 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[®] Lotion is available in 15 ml HDPE white flat bottle with flip top cap.

Marketed by:

Biocon Biologics India Limited

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

® - Registered trademark

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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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