For the use of only a Registered Medical Practitioner or Hospital or Laboratory

Biocon

Calcipotriol Ointment IP 0.005% w/w

CALPSOR® कैल्पसोर

Composition:
Calcipotriol anhydrous IP 0.005% w/w
Excipients Q.S.

DESCRIPTION
A synthetic vitamin D3 derivative, for topical dermatological use.

ATC Code: D05AX02

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
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 gm 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.
2. Use of Calcipotriol may cause irritation of lesions and surrounding uninvolved skin. If irritation develops, Calcipotriol should be discontinued.
3. 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 :
Pregnancy Category C
There are no adequate and well-controlled studies in pregnant women. Therefore, Calpsor® Ointment should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus

Lactation: It is not known whether calcipotriol is excreted in human milk. The systemic disposition of calcipotriol is expected to be similar to that of the naturally occurring vitamin because many drugs are excreted in human milk, caution should be exercised when Calcipotriol , 0.005% cream is administered to a nursing woman.

For the use of only a Registered Medical Practitioner or Hospital or Laboratory

Biocon

Calcipotriol Ointment IP 0.005% w/w

CALPSOR® कैल्पसोर

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.

Geriatric:
There were no significant differences in adverse events for subjects over 65 years compared to those under 65 years of age. However, the greater sensitivity of older individuals cannot be ruled out.

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.

SHELF LIFE: Please refer carton/ Tube

STORAGE
Store at a temperature not exceeding 25°C. Do not refrigerate or freeze.
Replace cap tightly after use. Keep out of reach of children

PRESENTATION
CALPSOR® is available in aluminum tube with screw cap.

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

® - Registered trademark

Leaflet Revised: July 2020

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**

BF/LL/4006/01