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

Biocon

℞

Clobetasol Propionate 0.05% w/w and Calcipotriol 0.005% w/w Ointment

CALPSOR® C कैल्पसोर सी

COMPOSITION:

Clobetasol Propionate IP	0.05% w/w
Calcipotriol IP	0.005% w/w
Excipients	Q.S

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

ATC Code: D05AX52

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. Calcitriol (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
Psoriasis vulgaris.

DOSAGE AND ADMINISTRATION
CALPSOR® C should be applied to the affected area once daily for up to 4 weeks. The maximum daily dose should not exceed 15g. The maximum weekly dose should not exceed 100g and the treated area should not be more than 30% of the body surface.

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.

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
If Calcipotriol and Clobetasol Propionate is used in excess of the maximum recommended weekly amount of 100 g, it is important to monitor the serum calcium levels at regular intervals due to the risk of hypercalcemia secondary to excessive absorption of Calcipotriol. If the serum calcium level becomes elevated, therapy should be discontinued and the serum calcium level monitored until it returns to normal.

Pregnancy and Lactation
There are no adequate and well-controlled studies in pregnant women. Therefore, ointment should not be used during pregnancy unless a potential benefit justifies the potential risk.

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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 (i.e. greater than the recommended weekly amount of 100 gm ointment or 5 mg Calcipotriol).

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 (more than 100g 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.

SPECIAL PRECAUTIONS FOR DISPOSAL AND OTHER HANDLING:
The unused drug product to be disposed off in accordance with local regulatory requirement

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

BF/LL/4005/01

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**