Betameson® -CL

Betamethasone & Clotrimazole

COMPOSITION

Betameson-CL™ Cream: Each gram cream contains Betamethasone 0.50 mg as Betamethasone Dipropionate BP & Clotrimazole BP 10 mg.

PHARMACOLOGY

Clotrimazole is a broad-spectrum antifungal agent used for the treatment of superficial infections caused by species of pathogenic dermatophytes, yeasts and *Malassezia furfur.* The mechanism of action involves inhibition of the synthesis of ergosterol, a major sterol in the fungal cell membrane. This leads to instability of the cell membrane and eventual death of the fungus. Betamethasone dipropionate is a corticosteroid with anti-inflammatory, antipruritic, and vasoconstrictive properties. But the exact mechanism of action of corticosteroids is not clearly known.

INDICATION

Betameson-CL™ Cream is indicated for the topical treatment of inflammatory dermal infections like tinea pedis, tinea cruris, tinea corporis, etc.

DOSAGE AND ADMINISTRATION

Sufficient cream should be applied onto the affected and surrounding skin areas twice a day, in the morning and evening, for 2 weeks in tinea cruris and tinea corporis and for 4 weeks in tinea pedis. The use of cream for longer than four weeks is not recommended.

CONTRAINDICATION AND PRECAUTION

The preparation is contraindicated to those patients who are sensitive to any of its components or to other corticosteroids or to imidazoles. If irritation or sensitization develops with the use of the cream, treatment should be discontinued and appropriate therapy instituted. The cream is contraindicated in facial rosacea, acne vulgaris, perioral dermatits, perianal and genital pruritus, napkin eruptions and bacterial or viral infections. Systemic absorption of topical corticosteroides can produce reversible hypothalmic-pituitary-adrenal (HPA) axis suppression. If HPA axis suppression is noted, an attempt should be made to withdraw the drug or to reduce the frequency of application. Pediatric patients may be more susceptible to systemic toxicity from equivalent doses due to their large skin surface to body mass ratios.

SIDE EFFECT

Adverse reactions reported for the preparation in clinical trials were paresthesia in 1.9% of patients, rash, edema and secondary infection, each in less than 1% of patients. Other adverse reactions reported with the preparation were burning and dry skin in 1.6% of patients and stinging in less than 1% of patients.

DRUG INTERACTION

No information is available.

USE IN PREGNANCY AND LACTATION

There is inadequate evidence of safety in pregnancy. Clotrimazole has no teratogenic effect in animals, but is foetotoxic at high oral doses. Topical administration of corticosteroids to pregnant animals can cause abnormalities of fetal development. Hence the cream should only be used in pregnancy, if the benefit justifies the potential risk to the fetus and such use should not be extensive, i.e. in large amounts or for long periods. It is not known whether the components of the preparation are excreted in human milk and therefore caution should be exercised when treating nursing mothers.

USE IN CHILDREN

The safety and effectiveness of the preparation has not been established in children below the age of 12 years.

OVERDOSE

Acute overdose with the cream is unlikely and would not be expected to lead to a life-threatening situation. The cream should not be used for longer than the prescribed time period.

STORAGE CONDITION

Store below 30˚C., protect from light. Do not freeze.

HOW SUPPLIED

Betameson-CL™ Cream : Each pack has a laminated tube containing 15 gm cream.

Manufactured by

SQUARE

PHARMACEUTICALS LTD.

BANGLADESH