

Betson-CL[®]

Betamethasone + Clotrimazole

Description : 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 is a corticosteroid with anti-inflammatory, antipruritic and vasoconstrictive properties. But the exact mechanism of action of corticosteroids is not clearly known.

Composition

Betson-CL[®] 20 gm Cream: Each gm cream contains Betamethasone Dipropionate BP 0.643 mg equivalent to Betamethasone 0.5 mg and Clotrimazole USP 10 mg.

Betson-CL[®] 20 gm Ointment: Each gm ointment contains Betamethasone Valerate BP 1.21 mg equivalent to Betamethasone 1 mg and Clotrimazole USP 10 mg.

Indications: This preparation is indicated for the topical treatment of inflammatory dermal infections like tinea pedis, tinea cruris, tinea corporis, etc.

Dosage & administration: Sufficient amount should be applied on 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 preparation for longer than four weeks is not recommended.

Contraindications: 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 preparation, treatment should be discontinued and appropriate therapy instituted. The preparation is contraindicated in facial rosacea, acne vulgaris, perioral dermatitis, perianal and genital pruritus, napkin eruptions and bacterial or viral infections.

Side effects: 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.

Use in pregnancy & lactation

Pregnancy

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 preparation 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.

Lactation

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.

Precautions : Systemic absorption of topical corticosteroids can produce reversible hypothalamic-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.

Drug interactions: No information is available.

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

Storage: Keep out of reach of children. Store in a dry place, below 25°C temperature and protected from light.

Packaging

Betson-CL[®] 20 gm Cream: Each carton contains 20 gm cream in lami tube.

Betson-CL[®] 20 gm Ointment: Each carton contains 20 gm ointment in lami tube.



Manufactured by
Opsonin Pharma Limited
Rupatali, Barishal, Bangladesh.
® Registered Trade Mark.

1020-01