

Topibet CL[®]

Betamethasone Valerate BP & Clotrimazole USP Ointment

DESCRIPTION

Topibet CL[®] ointment is a preparation of Betamethasone Valerate and Clotrimazole. Clotrimazole is a broad spectrum antifungal agent which is also active against Trichomonas, Staphylococci, Streptococci and Bacteroides. Betamethasone Valerate is a potent topical corticosteroid with very high vasoconstricting index. It reduces inflammation and also is antipruritic in action.

INDICATIONS

Topibet CL[®] ointment is recommended in the treatment of skin infection due to dermatophytes, yeasts, moulds and other fungi requiring rapid relief from symptoms of inflammation e.g. itching.

DOSAGE & ADMINISTRATION

Topibet CL[®] ointment should be thinly applied on the affected area twice daily, and rubbed in gently. Duration of treatment may be at least 4 weeks for inflammatory dermatophyte infections, and at least two weeks for inflammatory candidal infections.

CONTRAINDICATIONS

Hypersensitivity to any active ingredients of this preparation.

PRECAUTIONS

In common with all corticosteroids, long term use to extensive surface area of the skin should be avoided especially in infants and young children. In infants the napkin may act as occlusive dressings and increase its absorption.

SIDE-EFFECTS

Rarely local mild irritation or burning sensation may happen immediately after applying the ointment. In extremely rare case the patient may have to stop treatment due to intolerable irritation.

USE IN PREGNANCY AND LACTATION

In animals studies it has been found that topical administration of corticosteroids can cause abnormalities of foetal development. The relevance of this finding to humans has not been established.

In animal studies Clotrimazole is not found to have teratogenic effects but following oral administration in high dosage there is evidence of foetotoxicity in rats. The relevance of this finding to topical use in humans is not known. However, Clotrimazole has been used in pregnant patients for more than decade without attributable adverse effects.

Topibet CL[®] ointment should be used in pregnant patients only when considered essential by the physician.

PHARMACEUTICAL PRECAUTION

Store in a dry place and away from light. Keep out of reach of children.

PACKAGING

Topibet CL[®] ointment : Tube containing 10 g ointment. Each gram ointment contains Betamethasone Valerate BP equivalent to Betamethasone 1 mg and Clotrimazole USP 10 mg.

SK+F

Manufactured by

ESKAYEF PHARMACEUTICALS LTD.

GAZIPUR, BANGLADESH

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