Eczacort Cream

Hydrocortisone Butyrate USP 0.1%

Composition
Eczacort Cream: Each gram cream contains Hydrocortisone Butyrate USP 1 mg.

Pharmacology:
Topical corticosteroids share anti-inflammatory, antipruritic, and vasoconstrictive properties. Corticosteroids are thought to act by the induction of phospholipase A2 inhibitory proteins, collectively called lipocortins. It is postulated that these proteins control the biosynthesis of potent mediators of inflammation such as prostaglandins and leukotrienes by inhibiting the release of their common precursor, arachidonic acid. Arachidonic acid is released from membrane phospholipids by phospholipase A2.

Indications and usage
Hydrocortisone Butyrate is a topical corticosteroid indicated for relief of the inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses in adults. The topical treatment of mild to moderate atopic dermatitis in pediatric patients 3 months to 18 years of age.

Dosage and administration
For corticosteroid-responsive dermatoses in adults, apply a thin film to the affected skin areas two or three times daily, depending on the severity of the condition, and rub in gently. For atopic dermatitis in patients 3 months to 18 years of age, apply a thin film to the affected skin areas two times daily, and rub in gently. Do not apply hydrocortisone butyrate in the diaper area unless directed by a physician. Discontinue therapy when control is achieved. If no improvement is seen within 2 weeks, reassessment of the diagnosis may be necessary. Before prescribing for more than 2 weeks, any additional benefits of extending treatment to 4 weeks should be weighed against the risk of HPA axis suppression and local adverse events. The safety and efficacy of hydrocortisone butyrate has not been established beyond 4 weeks of use. Do not use hydrocortisone butyrate with occlusive dressings unless directed by a physician. Avoid use in the diaper area, as diapers or plastic pants may constitute occlusive dressings.

Contraindications
Hydrocortisone Butyrate is contraindicated in those patients with a history of sensitivity reactions to any of its active ingredients

Precautions
Systemic absorption of topical corticosteroids has produced reversible hypothalamic-pituitary-adrenal (HPA) axis suppression, manifestations of Cushing's syndrome, hyperglycemia, and glucosuria in some patients. Conditions which augment systemic absorption include the application of the more potent corticosteroids, use over large surface areas, prolonged use, and the addition of occlusive dressings. Children may absorb proportionally larger amounts of topical corticosteroids and thus be more susceptible to systemic toxicity. If irritation develops, topical corticosteroids should be discontinued and appropriate therapy instituted. In the presence of dermatological infections, the use of an appropriate antifungal or antibacterial agent should be instituted. If a favorable response does not occur promptly, the corticosteroid should be discontinued until the infection has been adequately controlled.

Side effects
Stinging, burning, itching, irritation, dryness, or redness at the application site may occur when this medication is first applied to the skin. These effects should disappear in a few days as body adjusts to the medication.

Drug interactions
There are no known drug interactions with Hydrocortisone Butyrate.

Pregnancy & lactation
Pregnancy:
There are no adequate and well-controlled studies in pregnant women. Therefore, Hydrocortisone Butyrate should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. Corticosteroids have been shown to be teratogenic in laboratory animals when administered systemically at relatively low dosage levels. Some corticosteroids have been shown to be teratogenic after dermal application in laboratory animals.
Lactation:
It is not known whether topical administration of corticosteroids could result in sufficient systemic absorption to produce detectable quantities in breast milk. Systemically administered corticosteroids are secreted into breast milk, in quantities not likely to have a deleterious effect on the infant. Nevertheless, caution should be exercised when topical corticosteroids are administered to a nursing woman.

Pediatric use
Safety and efficacy in pediatric patients below 3 months of age have not been established.

Geriatric use
Safety and efficacy in geriatric patients over 65 years of age have not been established.

Storage
Do not store above 25°C. Protect from light. Do not freeze. Keep out of reach of children

Packaging
Eczacort Cream: Each carton contains a tube of 30 g cream.

Manufactured by
ZISKA PHARMA
Ziska Pharmaceuticals Ltd.
Kaliakoir, Gazipur, Bangladesh