HYDROCORTISONE

ECZACORT®

10 mg/g Cream
Corticosteroid

℞

FORMULATION
Each gram contains:
Hydrocortisone..... 10 mg

The topical corticosteroids constitute a class of primarily synthetic steroids used as anti-infammatory and antipruritic agents.

INDICATION
Topical corticosteroids are indicated for the relief of the inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses.

CONTRAINDICATION
Topical corticosteroids are contraindicated in those patients with a history of hypersensitivity to any components of the preparation.

ACTION
Topical corticosteroids share anti-inflammatory, antipruritic and vasoconstrictive actions. The mechanism of anti-inflammatory activity of the topical corticosteroids is unclear. Various laboratory methods, including vasoconstrictor assays, are used to compare and predict potencies and/or clinical efficacies of the topical corticosteroids. There is some evidence to suggest that a recognizable correlation exists between vasoconstrictor potency and therapeutic efficacy in man.

DOSAGE AND ADMINISTRATION
Hydrocortisone Cream should be applied to the affected area two to four times daily depending on the severity of the condition. Or as prescribed by the physician.

Occlusive dressings may be used for the management of psoriasis or recalcitrant conditions. If an infection develops, the use of occlusive dressings should be discontinued and appropriate antimicrobial therapy instituted.

OVERDOSAGE
Topically applied corticosteroids can be absorbed in sufficient amounts to product systemic effects.

PHARMACOKINETICS
The extent of percutaneous absorption of topical corticosteriods is determined by many factors including the vehicle, the integrity of the epidermal barrier, and the use of occlusive dressings.

Topical corticosteriods can be absorbed from normal intact skin. Inflammation and/or other disease processes in the skin increase percutaneous absorption. Occlusive dressings substantially increase the percutaneous absorption of topical corticosteriods. Thus, occlusive dressings may be a valuable therapeutic adjunct for treatment of resistant dermatoses.

Once absorbed through the skin, topical corticosteriods are handled through pharmacokinetic pathways similar to systematically administered corticosteriods. Corticosteriods are bound to plasma proteins in varying degress.

Corticosteriods are metabolized primarily in the liver and are then excreted by the kidneys. Some of the topical corticosteriods and their metabolites are also excreted in the bile

ADVERSE EFFECT
The following local adverse reactions are reported infrequently with topical corticosteroids, but may occur more frequently with the use of occlusive dressings. These reactions are listed in an approximate decreasing order of occurrence: burning, itching, irritation, dryness, folliculitis, hypertrichosis, acneiform eruptions, hypopigmentation, perioral dermatitis, allergic contact dermatitis, maceration of the skin, secondary infection, skin atrophy, striae, and miliaria.

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 steroids use over large surface areas, prolonged use, and the addition of occlusive dressings.

If HPA axis suppression is noted (by using the urinary free cortisol and ACTH stimulation tests) an attempt should be made to withdraw the drug or to reduce the frequency of application. Recovery of HPA axis function is generally prompt and complete upon discontinuation of the drug. Infrequently, signs and symptoms of steroid withdrawal may occur, requiring supplemental systemic corticosteroids.

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.

Pregnancy Category C: Corticosteriods are generally teratogenic in laboratory animals when administered systemically at relatively low dosage levels. However, there are no adequate and well-controlled studies in pregnant women on teratogenic effects from topically applied corticosteriods. Therefore, topical corticosteriods should be used during pregnancy only if the potential benefit justifies the potential risk of the fetus. Drugs of this class should not be used extensively on pregnant patients, in large amounts, or for prolonged periods of time.

Nursing Mothers: It is not known whether topical administration of corticosteriods could result in sufficient systemic absorption to produce detectable quantities in breast milk. Systematically administered corticosteriods are secreted into breast milk in quantities not likely to have a deleterious affect on the infant. Nevertheless, caution should be exercised when topical corticosteriods are administered to a nursing woman.

Use in Pediatric Patients: Pediatric patients may absorb proportionally larger amounts of topical corticosteriods (due to large skin surface areas to body weight ratio) and thus be more susceptible to systemic toxicity.

Administration of topical corticosteroids to pediatric patients should be limited to the least amount compatible with an effective therapeutic regimen. Chronic corticosteroid therapy may interfere with the growth and development of pediatric patients which include linear growth retardation, delayed weight gain, low plasma cortisol levels, and absence of response to ACTH stimulation.

STORAGE
Store at temperatures not exceeding 25°C.

CAUTION
Foods, Drugs, Devices and Cosmetics Act prohibits dispensing without prescription.

AVAILABILITY
Hydrocortisone (Eczacort®) Cream in aluminum plastic laminated tubes of 10g.

Manufactured by
Interphil Laboratories, Inc.
Canlubang Industrial Estate, Bo. Pittland
Cabuyao, Laguna, Philippines
Distributed by
United Laboratories, Inc.
66 United St., Mandaluyong City, Philippines
Under Authority by
PEDIATRICA, INC.
3/F Bonaventure Plaza, Ortigas Avenue
Greenhills, San Juan City, Philippines

Reg. IPOPHIL

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