**DESCRIPTION:**

Cloderm Cream 0.1% contains the medium potency topical corticosteroid clocortolone pivalate in a specially formulated water-washable emollient cream base containing purified water, white petrolatum, mineral oil, alcohol, polyethylene 40 stearate, carbon black, clocortolone pivalate, sodium hydroxide, and propylparaben as preservatives. It is inactive when first opened. The mechanism of anti-inflammatory activity of the topical corticosteroids is unclear. Various laboratory methods, including vasomotor and arachidonic acid assays, are used to compare and predict potencies and/or clinical efficacies of the topical corticosteroids. There is some evidence to suggest that a reversible correlation exists between vasomotor potency and therapeutic efficacy in man.

**CLINICAL PHARMACOLOGY:**

Topical corticosteroids share anti-inflammatory, antiproliferative and vasoconstrictive actions.

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

**PRECAUTIONS - Pediatric Use:**

Pediatric patients may demonstrate greater susceptibility to systemic toxicity than adults. Topical corticosteroids may be absorbed from the skin in sufficient amounts to produce detectable quantities in the blood.

**ADVERSE REACTIONS:**

Skin reactions and systemic absorption of corticosteroids can occur simultaneously. These reactions may be characterized by pruritus, irritability, drowsiness, and adrenocortical insufficiency in infants and children. The mechanism of action is unknown, but it may involve direct inhibition of allergen-induced responses and/or suppression of cutaneous immune responses.

**DOSAGE AND ADMINISTRATION:**

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

**CONTRAINDICATIONS:**

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

**INDICATIONS AND USAGE:**

Topical corticosteroids are indicated for the relief of the inflammatory and pruritic manifestations of cutaneous-responsive dermatoses. These conditions usually present a complex picture in which a dermatosis appears as an integral part of a systemic disease. The role of corticosteroids is to ameliorate symptoms and promote healing. In the presence of dermatological infections, the use of an appropriate antibacterial or antifungal agent should be instituted. If a favorable response does not occur promptly, the corticosteroid should be discontinued and the patient referred to a physician for evaluation of the infection.

**OVERDOSAGE:**

Overdosage may occur when a large dose of a potent topical steroid is used on a large surface area or under occlusive dressings. Overdosage may also occur when occlusive dressings are used for an extended period of time. Overdosage may result in the development of skin atrophy. The use of occlusive dressings with the medium potency topical corticosteroids is contraindicated in those patients with a history of hypersensitivity to any of the components of the preparation.

**REFERENCES:**

Corticosteroids are absorbed from the skin in sufficient amounts to produce detectable quantities in the blood.

**STORAGE:**

Store Cloderm Cream between 15° and 30° C (59° and 86° F). Avoid freezing.

**HOW SUPPLIED:**

Cloderm (clocortolone pivalate) Cream 0.1% is supplied in 75 gram pump bottles, 45 gram and 90 gram tubes.

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