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# PERDERM* Cream/Ointment

*Schering-Plough*

Brand of alclometasone dipropionate
FOR DERMATOLOGIC USE ONLY

## DESCRIPTION

Each gram of PERDERM Cream 0.05% contains 0.5 mg alclometasone dipropionate in a hydrophilic emollient cream vehicle containing propylene glycol, chlorocresol, sodium phospate (monobasic, monohydrate), phosphoric acid, polyoxyethylene (20) cetyl ether, glyceryl stearate PEG 100 stearate, white petrolatum, cetostearyl alcohol and purified water

Each gram of PERDERM Ointment 0.05% contains 0.5 mg alclometasone dipropionate in an ointment vehicle containing hexylene glycol, propylene glycol monostearate, white wax and white petrolatum.

## ACTIONS

Alclometasone dipropionate is a nonfluorinated, synthetic corticosteroid with anti-inflammatory, antipruritic and vasoconstrictive properties.

## INDICATIONS AND USAGE

PERDERM Products are indicated for the relief of the inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses.

## DOSAGE AND ADMINISTRATION

A thin film of PERDERM Cream or Ointment should be applied to affected skin areas two or three times daily; massage gently until the medication disappears.

## ADVERSE REACTIONS

Reported rarely with alclometasone are itching, burning, erythema, dryness, irritation and papular rashes. Other local adverse reactions associated with topical corticosteroids, especially under occlusive dressings, include folliculitis, hypertrichosis, acneiform eruptions, hypopigmentation, perioral dermatitis, allergic contact dermatitis, skin maceration, secondary infection, skin atrophy, striae and miliaria.

## CONTRAINDICATIONS

PERDERM Products are contraindicated in those patients with a history of sensitivity reactions to any of their components or to other corticosteroids.

## PRECAUTIONS

If irritation or sensitization develops with the use of PERDERM Products, treatment should be discontinued and appropriate therapy instituted.

In the presence of infection, an appropriate antifungal or antibacterial agent should be administered. If a favorable response does not occur promptly, the corticosteroid should be discontinued until the infection has been controlled adequately.

Systemic absorption of topical corticosteroids may be increased if extensive body surface areas are treated or if the occlusive technique is used. Suitable precautions should be taken under these conditions or when long-term use is anticipated, particularly in infants and children.

Any of the side effects that are reported following systemic use of corticosteroids, including adrenal suppression, may also occur with topical corticosteroids, especially in infants and children.

PERDERM Products are not for ophthalmic use.

### Pediatric Use

Pediatric patients may demonstrate greater susceptibility to topical corticosteroid-induced hypothalamic-pituitary-adrenal (HPA) axis suppression and to exogenous corticosteroid effects than mature patients because of greater absorption due to a large skin surface area to body weight ratio, HPA axis suppression, Cushing's syndrome, linear growth retardation, delayed weight gain, and intracranial hypertension have been reported in children receiving topical corticosteroids. Manifestations of adrenal suppression in children include low plasma cortisol levels and absence of response to ACTH stimulation. Manifestations of intracranial hypertension include a bulging fontanelle, headaches and bilateral papilledema.

## USE DURING PREGNANCY AND IN NURSING WOMEN

Since safety of topical corticosteroid use in pregnant women has not been established, drugs of this class should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. Drugs of this class should not be used extensively in large amounts or for prolonged periods of time in pregnant patients.

Since it is not known whether topical administration of corticosteroids can result in sufficient systemic absorption to produce detectable quantities in breast milk, a decision should be made to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

## OVERDOSAGE

Acute overdosage with dermatologic application of corticosteroids is unlikely and would not be expected to lead to a life-threatening situation.

### Symptoms

Excessive or prolonged use of topical corticosteroids can suppress pituitary-adrenal function, resulting in secondary adrenal insufficiency, and produce manifestations of hypercorticism, including Cushing's disease.

### Treatment

Appropriate symptomatic treatment is indicated. Acute hypercorticoid symptoms are usually reversible. Treat electrolyte imbalance, if necessary. In case of chronic toxicity, slow withdrawal of corticosteroids is advised.

## HOW SUPPLIED

PERDERM Cream, tubes of 10 and 30 gm.
PERDERM Ointment, tubes of 10 and 30 gm.

## STORAGE

Store between 2°C and 30°C

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