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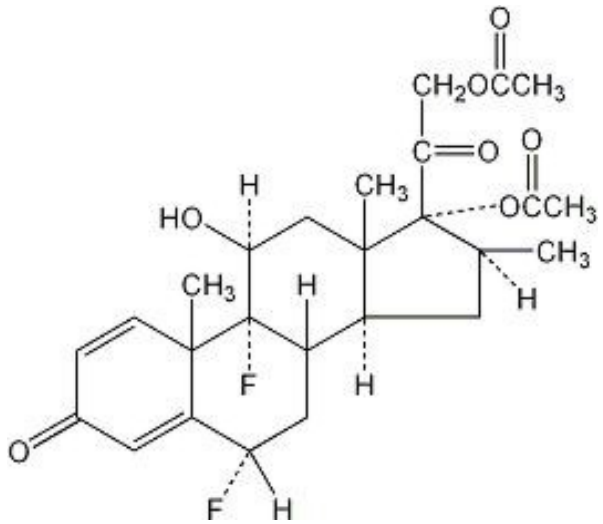
PSORCON® E Emollient Ointment
(diflorasone diacetate ointment) 0.05%

For Topical Use
Not For Ophthalmic Use

DESCRIPTION

Each gram of **Psorcon E** Emollient Ointment contains 0.5 mg diflorasone diacetate in an ointment base. Chemically, diflorasone diacetate is: 6α,9-difluoro-11β,17,21-trihydroxy-16β-methyl-pregna-1,4-diene-3,20-dione 17,21-diacetate. The structural formula is represented below:



Psorcon E Emollient Ointment contains diflorasone diacetate in an emollient, occlusive base consisting of polyoxypropylene 15-stearyl ether, stearic acid, lanolin alcohol and white petrolatum.

CLINICAL PHARMACOLOGY

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.

Pharmacokinetics: 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.

Topical corticosteroids can be absorbed from normal intact skin. Inflammation and/or other disease processes in the skin increase percutaneous absorption. Occlusive dressings

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substantially increase the percutaneous absorption of topical corticosteroids. Thus, occlusive dressings may be a valuable therapeutic adjunct for treatment of resistant dermatoses (see **DOSAGE AND ADMINISTRATION**).

Once absorbed through the skin, topical corticosteroids are handled through pharmacokinetic pathways similar to systemically administered corticosteroids. Corticosteroids are bound to plasma proteins in varying degrees. They are metabolized primarily in the liver and are then excreted by the kidneys. Some of the topical corticosteroids and their metabolites are also excreted into the bile.

INDICATIONS AND USAGE

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

CONTRAINDICATIONS

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

WARNINGS

Use of topical corticosteroids, including **Psorcon E** Emollient Ointment may increase the risk of posterior subcapsular cataracts and glaucoma. Cataracts have been reported in postmarketing experience with the use of topical diflorasone diacetate products. Glaucoma, with possible damage to the optic nerve, and increased intraocular pressure have been reported in postmarketing experience with the use of topical dermal corticosteroids.

Avoid contact of **Psorcon E** Emollient Ointment with eyes. Advise patients to report any visual symptoms.

PRECAUTIONS

General: 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.

Therefore, patients receiving a large dose of a potent topical steroid applied to a large surface area or under an occlusive dressing should be evaluated periodically for evidence of HPA axis suppression by using the urinary free cortisol and ACTH stimulation tests. If HPA axis suppression is noted, an attempt should be made to withdraw the drug, to reduce the frequency of application, or to substitute a less potent steroid.

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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.

Pediatric patients may absorb proportionally larger amounts of topical corticosteroids and thus be more susceptible to systemic toxicity (see **PRECAUTIONS: Pediatric Use**).

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.

Information for the Patient: Patients using topical corticosteroids should receive the following information and instructions:

1. This medication is to be used as directed by the physician. It is for external use only. Avoid contact with the eyes.
2. Patients should be advised not to use this medication for any disorder other than for which it was prescribed.
3. Contact your healthcare provider if you experience blurred vision or other visual disturbances (see **WARNINGS**).
4. The treated skin area should not be bandaged or otherwise covered or wrapped as to be occlusive unless directed by the physician (see **PRECAUTIONS**).
5. Patients should report any signs of local adverse reactions especially under occlusive dressing.
6. Parents of pediatric patients should be advised not to use tight-fitting diapers or plastic pants on an infant or child being treated in the diaper area, as these garments may constitute occlusive dressings.

Laboratory Tests: The following tests may be helpful in evaluating the HPA axis suppression:

Urinary free cortisol test
ACTH stimulation test

Carcinogenesis, Mutagenesis, and Impairment of Fertility: Long-term animal studies have not been performed to evaluate the carcinogenic potential or the effect on fertility of topical corticosteroids.

Diflorasone diacetate was not mutagenic in a micronucleus test in rats at intraperitoneal doses up to 2400 mg/kg.

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Pregnancy: Corticosteroids are generally teratogenic in laboratory animals when administered systemically at relatively low dosage levels. The more potent corticosteroids have been shown to be teratogenic after dermal application in laboratory animals. There are no adequate and well-controlled studies in pregnant women on teratogenic effects from topically applied corticosteroids. Therefore, topical corticosteroids 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 on pregnant patients, in large amounts, or for prolonged periods of time.

Nursing Mothers: It is not known whether topical administration of corticosteroids could result in sufficient systemic absorption to produce detectable quantities in breast milk. Because many drugs are excreted in human milk, caution should be exercised when **Psorcon E** Emollient Ointment is administered to a nursing woman.

Pediatric Use: Safety and effectiveness of **Psorcon E** (diflorasone diacetate ointment) in pediatric patients have not been established. Because of a higher ratio of skin surface area to body mass, pediatric patients are at a greater risk than adults of HPA-axis suppression when they are treated with topical corticosteroids. They are, therefore, also at greater risk of glucocorticosteroid insufficiency after withdrawal of treatment and of Cushing's syndrome while on treatment. Adverse effects including striae have been reported with inappropriate use of topical corticosteroids in pediatric patients.

HPA axis suppression, Cushing's syndrome, and intracranial hypertension have been reported in pediatric patients receiving topical corticosteroids. Manifestations of adrenal suppression in pediatric patients include linear growth retardation, delayed weight gain, low plasma cortisol levels, and absence of response to ACTH stimulation. Manifestations of intracranial hypertension include bulging fontanelles, headaches, and bilateral papilledema.

Geriatric Use: Clinical studies of diflorasone diacetate topical formulations did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects.

ADVERSE REACTIONS

The following adverse reactions have been identified from clinical trials or postmarketing surveillance. Because they are reported from a population from unknown size, it is not always possible to reliably estimate their frequency or establish a causal relationship to topical corticosteroids exposure.

These adverse reactions may occur more frequently with the use of occlusive dressings or prolonged use of topical corticosteroids.

Skin and Subcutaneous Tissue Disorders: 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

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Vision Disorders*:* cataract, glaucoma, central serous chorioretinopathy

OVERDOSAGE

Topically applied corticosteroids can be absorbed in sufficient amounts to produce systemic effects (see **PRECAUTIONS**).

DOSAGE AND ADMINISTRATION

Topical corticosteroids should be applied to the affected area as a thin film from one to four times daily depending on the severity of the condition.

For topical use only. Avoid contact with eyes.

Wash hands after each application.

Do not use with occlusive dressings, unless directed by a physician (see **PRECAUTIONS**).

If an infection develops, the use of occlusive dressings should be discontinued and appropriate antimicrobial therapy initiated.

HOW SUPPLIED

Psorcon E Emollient Ointment is available as follows:

15 gram tube	NDC 0066–0275–17
30 gram tube	NDC 0066–0275–31
60 gram tube	NDC 0066–0275–60

Store at controlled room temperature, 20° to 25° C (68° to 77° F) [see USP].

Rx only

Manufactured for
Dermik Laboratories, Inc.
Berwyn, PA USA 19312
By Pharmacia & Upjohn Company
A Division of Pfizer Inc
Kalamazoo, MI, USA 49001

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