DESCRIPTION
Topicort® LP (desoximetasone) Cream 0.05%; Topicort® (desoximetasone) Gel 0.05%; and Topicort® (desoximetasone) Ointment 0.25% contain the active synthetic corticosteroid desoximetasone. The topical corticosteroids constitute a class of primarily synthetic steroids used as anti-inflammatory and antipruritic agents. Each gram of Topicort® LP Cream 0.05% contains 0.5 mg of desoximetasone in an emollient cream base consisting of white petrolatum, purified water, isopropyl myristate, lanolin alcohols, mineral oil, cetylstearyl alcohol, and adenosine diphosphoric acid. Each gram of Topicort® Cream 0.05% contains 0.25 mg of desoximetasone in an emollient cream base consisting of white petrolatum, purified water, isopropyl myristate, lanolin alcohols, mineral oil, and cetylstearyl alcohol. Each gram of Topicort® Gel 0.05% contains 0.5 mg of desoximetasone in a gel base consisting of purified water, docusate sodium, edetate disodium, isopropyl myristate, carbomer (4%), triethanolamine, and ISDA-3 (0.5%) alcohol. Each gram of Topicort® Ointment 0.25% contains 2.5 mg of desoximetasone in an ointment base consisting of white petrolatum and fractionated coconut oil. The chemical name of desoximetasone is 17α-fluoro-11,21-dihydroxy-16-α,17β-dihydroxy-Pregna-1,4-diene-3,20-dione. Desoximetasone has the chemical formula C_{22}H_{29}FO_{4} and a molecular weight of 376.47. The CAS Registry Number is 382-67-2.

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 substantially increase the percutaneous absorption of topical corticosteroids. Thus, occlusive dressings may be a valuable therapeutic adjunct for treatment of resistant dermatoses. 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. Corticosteroids 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. Pharmacokinetic studies in men with Topicort® (desoximetasone) Cream 0.05% with tagged desoximetasone showed a total of 9.2% ± 2.9% excretion in urine (4.1% ± 2.3%) and feces (1.1% ± 0.6%) and no detectable level (limit of sensitivity: 0.005 µg/mL) in the blood when it was applied topically on the back followed by occlusion for 24 hours. The extent of absorption for the ointment was 7% based on radioactivity recovered from urine and feces. Seven days after application, no further radioactivity was detected in urine or feces. The half-life of the material was 16 ± 2 hours (for urine) and 17 ± 2 hours (for feces) between the third and fifth trial day. Pharmacokinetic studies in men with Topicort® (desoximetasone) Ointment 0.25% with tagged desoximetasone showed no detectable level (limit of sensitivity: 0.003 µg/mL) in 1 subject and 0.004 and 0.006 µg/mL in the remaining 2 subjects in the blood when it was applied topically on the back followed by occlusion for 24 hours. The extent of absorption for the ointment was 7% based on radioactivity recovered from urine and feces. Seven days after application, no further radioactivity was detected in urine or feces. Studies with other similarly structured steroids have shown that predominant metabolite reaction occurs through conjugation to form the glucuronide and sulfate ester.

INDICATIONS AND USAGE
Topicort® LP (desoximetasone) Cream 0.05%; Topicort® (desoximetasone) Cream 0.25%; Topicort® (desoximetasone) Gel 0.05%; and Topicort® (desoximetasone) Ointment 0.25% are indicated for the relief of the inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses.

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

WARNINGS
Topicort® LP (desoximetasone) Cream 0.05%; Topicort® (desoximetasone) Cream 0.25%; Topicort® (desoximetasone) Gel 0.05%; and Topicort® (desoximetasone) Ointment 0.25% are not for ophthalmic use.

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.

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.

Rx only
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 discon- tinued 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. 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. The treated skin area should not be bandaged or otherwise covered or wrapped as to be occlusive unless directed by the physician.
4. Patients should report any signs of local adverse reactions, especially under occlusive dressings.
5. Parents of pediatric patients should be advised not to use this medication on a 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 hypothalamic-pituitary-adrenal (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 fer-
tility of topical corticosteroids.

Studies to determine mutagenicity with prednisolone and hydrocortisone have revealed negative results. Desoximetasone did not show potential for mutagenic activity in vitro in the Ames microbial mutagen test with or without metabolic activation.

**Pregnancy. Teratogenic Effects. Pregnancy Category C**

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 appli-
cation in laboratory animals. Desoximetasone has been shown to be teratogenic and embryotoxic in mice, rats, and rabbits when given by subcutaneous or dermal routes of administration in doses 5 to 30 times the human dose of Topicort® (desoximetasone) Cream 0.05% or Topicort® (desoximetasone) Ointment 0.25% and 15 to 150 times the human dose of Topicort® LP (desoximetasone) Cream 0.05% or Topicort® (des-
oximetasone) Gel 0.05%. There are no adequate and well-controlled studies in pregnant women on terato-
genic effects from topically applied corticosteroids. Therefore, Topicort® LP Cream 0.05%, Topicort® Cream 0.25%, Topicort® Gel 0.05%, and Topicort® Ointment 0.25% 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. 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**

Pediatric patients may demonstrate greater susceptibility to topical corticosteroid-induced HPA axis suppression and Cushing’s syndrome than mature patients because of a larger skin surface area to body weight ratio.

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.

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. Safety and effectiveness of Topicort® Ointment in pediatric patients below the age of 10 have not been established.

**ADVERSE REACTIONS**

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
- Aceneform eruptions
- Hypopigmentation
- Pruritus
dermal dermatitis
- Skin atrophy
- Striae
- Allergic contact dermatitis
- Miliaria

In controlled clinical studies the incidence of adverse reactions was low (0.8%) for Topicort® (desoximetasone) Cream 0.05%, Topicort® (desoximetasone) Cream 0.25%, Topicort® (desoximetasone) Gel 0.05%, and Topicort® (desoximetasone) Ointment 0.25% to the affected skin areas twice daily. Rub in gently.

**OVERDOSAGE**

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

**DOSAGE AND ADMINISTRATION**

Apply a thin film of Topicort® LP (desoximetasone) Cream 0.05%, Topicort® (desoximetasone) Cream 0.25%, Topicort® (desoximetasone) Gel 0.05%, and Topicort® (desoximetasone) Ointment 0.25% to the affected skin areas twice daily. Rub in gently.

**HOW SUPPLIED**

Topicort® LP (desoximetasone) Cream 0.05% is supplied in 5 gram tubes for physician samples, 15 gram and 60 gram tubes.

Topicort® (desoximetasone) Cream 0.25% is supplied in 5 gram tubes for physician samples, 15 gram and 60 gram tubes.

Topicort® (desoximetasone) Gel 0.05% is supplied in 5 gram tubes for physician samples, 15 gram and 60 gram tubes.

Store at controlled room temperature 15˚ - 30˚C (59˚ - 86˚F).

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