TaroPharma

Topicort®
(DESOXIMETASONE)

The Widest Corticosteroid Family Available

TOPICORT® Cream 0.25%
• No Propylene Glycol, Parabens, or Fragrances
• Distinctive Water-In-Oil Base
• 15 and 60 g Tubes

TOPICORT® Gel 0.05%
• No Propylene Glycol, Parabens, or Fragrances
• Easy-to-Spread, Self-Liquefying Base
• 15 and 60 g Tubes

TOPICORT® Ointment 0.25%
• Occlusive Base With White Petrolatum and Beeswax
• Penetrates, Lubricates, Soothes and Moisturizes
• 15 and 60 g Tubes

TOPICORT® LP Cream 0.05%
• No Propylene Glycol, Parabens, or Fragrances
• Distinctive Water-In-Oil Base
• 15 and 60 g Tubes

TOPICORT® LP Ointment 0.05%
• Pediatric Indication up to 10 years old

CLASS II

CLASS III
**Topicort®**
(Desoximetasone) Cream 0.25%, LP Cream 0.05% and Gel 0.05%

**Effective and Well-Tolerated for the Treatment of Scalp Psoriasis and Dermatitis**

**Improvement Observed as Early as Day 4 for the Treatment of Scalp Psoriasis**

- By day 14, 89% of patients had an overall evaluation of excellent or good for Topicort gel 0.05%

- Safe and well-tolerated

- Cosmetically accepted

- Minimal adverse effects

**Superior Efficacy in Reducing Symptoms of Dermatitis after 3 Weeks of Use**

- Treatment with 0.25% Topicort produced greatest change in clinical symptoms

- Greatest improvement occurring during week 1

- Results suggest vehicle contributes significantly to clinical effect

- No adverse effects reported

**REFERENCES**
1. Willis, I., Cornell, R.C., Penneys, N. S., Zaias, N., Multicenter Study Comparing 0.05% Gel Formulations of Desoximetasone and Fluocinonide in Patients with Scalp Psoriasis. Clinical Therapeutics, 1986; 8(3):275-282.
2. Ashton, R. E., Catternall, M., et al., A Double-blind Comparison of 0.25% and 0.05% Desoxymethasone, 0.1% Betamethasone Valerate and 1% Hydrocortisone Creams in the Treatment of Eczema. The Journal of International Medical Research, 1987; 15:160-166.
Desoximetasone Ointment 0.25% and Tacrolimus Ointment 0.1% are Compatible Both Physically and Chemically up to 4 Weeks²

Chemical Compatibility

- HPLC method developed
- No significant difference in chromatographic profile between the mixture and individual ointments under 3 temperature/humidity conditions

![Graphs showing % Relative Recovery of Desoximetasone and Tacrolimus](#)

Variations seen are expected, and are due to the analytical procedure, not chemical incompatibility.

Physical Compatibility

- No significant difference in physical appearance between the mixture and individual ointments
- No more than slight separation was observed over any time period under any of the three storage conditions³

Significance

- Compatibility allows consideration of simultaneous application of desoximetasone ointment 0.25% and tacrolimus ointment 0.1%
- Theoretically, simultaneous application could decrease tacrolimus side effects and enable further steroid-sparing effect

1. Data on file, TARO PHARMACEUTICALS
2. * when mixed at a ratio of 1:1 (w/w)
3. Slight: trace of liquid observed which is free flowing, but an insufficient amount to do more than "wet" container walls
A name you can depend on

TOPICORT®
(DESOXIMETASONE)

FULL PREScribing INFORMATION
For Dermatologic Use Only • Not for Use In Eyes • Rx Only

DESCRIPTION:
TOPICORT Emulsion Cream 0.05%, TOPICORT Gel 0.05%, TOPICORT Ointment 0.05% and TOPICORT LP Emulsion 0.05% contain the active synthetic corticosteroid desoximetasone. The topical corticosteroids comprise a class of primarily synthetic steroids used as anti-inflammatory and anti-pruritic agents. Each gram of TOPICORT Emulsion Cream 0.05% contains 2.5 mg of Desoximetasone in an emulsion consisting of White Petroleum USP, Purified Water USP, Isopropanol Myristyl ether, Loxolin Alcohol USP, Mineral Oil USP, Cetyl Alcohol NF, Aluminum Stearate, and Magnesium Stearate.

Each gram of TOPICORT Gel 0.05% contains 0.5 mg desoximetasone in a gel consisting of Purified Water USP, SD Alcohol 40 (20% w/v), Isopropyl Myristate NF, Carbomer 940, Triethanolamine NF, Estesol Emulsion USP, and Docusate Sodium USP.

Each gram of TOPICORT Ointment 0.05% contains 2.5 mg of Desoximetasone in a base consisting of White Petroleum USP, Propylene Glycol USP, Stearic Sesquioleate, Beeswax, Dextrose Alcohol, Glycerol Monostearate Emulsion, and Redistilled Water. Each gram of TOPICORT LP Emulsion Cream 0.05% contains 0.5 mg desoximetasone in an emulsion consisting of White Petroleum USP, Purified Water USP, Isopropanol Myristyl ether, Lanolin Alcohol NF, Mineral Oil USP, Cetyl Alcohol NF, Aluminum Stearate, Estesol-65 USP, Loxolin Alcohol USP, and Magnesium Stearate.

The chemical name of desoximetasone is 16a-Hydroxy-21-chloro-11,17,21-trihydroxy-3,20-pregnadiene-1,4-dione and a molecular weight of 376.47. The CAS Registry Number is 352-67-2. The chemical structure is:

![Chemical Structure](image)

CLINICAL PHARMACOLOGY:
Topical corticosteroids are anti-inflammatory, anti-pruritic, and vasoconstrictive agents.

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. The relative potencies of topical corticosteroids are suggested to support the relative anti-inflammatory and anti-pruritic potency of topical corticosteroids.

PHARMACOKINETICS:
The extent of absorption of topical corticosteroids is determined by many factors, including the vehicle, the integrity of the epidermal barrier, and the site of application. 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.

Corticosteroids penetrate the skin by passive diffusion through the stratum corneum. They are also absorbed systemically to some extent. Corticosteroids are metabolized primarily in the liver and are excreted by the kidneys. Some of the topical corticosteroids are also excreted in the bile.

Pharmacokinetic studies in man with TOPICORT Emulsion Cream 0.05% with tagged desoximetasone showed a total of 5.0% ± 2.5% excretion in urine (4.5% 0.005% and 1.1% ± 0.8%) and no detectable level (limit of sensitivity: 0.005%g) of the blood when it was applied topically on the back followed by occlusion for 24 hours. Seven days after application, no further radioactivity was detected in urine or feces. The half-life of the material was 15 ± 2 hours (for urine) and 17 ± 2 hours (for feces). The second and fifth trial days showed similar results.

Pharmocokinetic studies in man with TOPICORT Ointment 0.05% with tagged desoximetasone showed no detectable level of desoximetasone in the blood on the third and fifth trial days after application of the ointment. On the second trial day, the desoximetasone level was 0.005%.

The absorption of the steroid 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 prednisolone metabolites react towards conjugation to form the glucuronide and sulphate ester.

INDICATIONS AND USE:
TOPICORT Emulsion Cream 0.05%, TOPICORT Gel 0.05%, TOPICORT Ointment 0.05% and TOPICORT LP Emulsion Cream 0.05% 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 Emulsion Cream 0.05%, TOPICORT Gel 0.05%, TOPICORT Ointment 0.05% and TOPICORT LP Emulsion Cream 0.05% are not for ophthalmic use. Keep out of reach of children.

PRECAUTIONS:
Systemic absorption of topical corticosteroids has produced reversible hypothalamic-pituitary-adrenal (HPA) axis suppression, manifestations of Cushings syndrome, hyperglycemia, and glucocorticosteroids in some patients. Conditions which augment systemic absorption include the application of the more potent steroids, ove 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 ACTH stimulation test. 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; frequently, signs and symptoms of steroid withdrawal may occur, requiring supplemental systemic corticosteroids.

Pediatric patients may absorb proportionally larger amounts of topical corticosteroids and be more susceptible to adrenocortical insufficiency (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 inappropriate 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.