Discard this product 30 days after dispensed by pharmacist.

5 (3.7%) Discontinue therapy when control is achieved. If no improvement is seen within 4 weeks, contact the physician.

This medication is flammable; avoid heat, flame, or smoking when applying this product.

11 DESCRIPTION

Each gram of Topicort® Topical Spray contains 2.5 mg of desoximetasone as the active ingredient. The structural formula is:

\[
\text{\begin{align*}
\text{H} & \quad \text{O} \\
\text{O} & \quad \text{H} \\
\text{H} & \quad \text{O} \\
\end{align*}}
\]

12 CLINICAL PHARMACOLOGY

12.1 Metabolism and Excretion

The principal route of metabolism is an enzyme-mediated hydroxylation of the 9-fluoro group, followed by a 21-hydroxylation. The biotransformation products have little or no effect on the pharmacological activity of desoximetasone. The products of biotransformation are excreted in the urine and feces. The excretion of metabolites is dose-related and increases with increasing dosage. The 21-hydroxylated metabolite of desoximetasone has been isolated from human urine, but its significance in vivo is not known.

12.2 Pharmacokinetics

The onset of percutaneous absorption of topical corticosteroids is determined by many factors including the vehicle, the intensity 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 that in the skin increase percutaneous absorption. Occlusive dressings substantially increase the percutaneous absorption of topical corticosteroids. Therefore, through the skin, corticosteroids are absorbed systemically in patients with extensive lesions in areas where the epidermal barrier may be impaired.

The percutaneous absorption of topical corticosteroids is increased in patients with severe and/or extensive skin disease, with increased skin permeability due to the condition or its treatment, or with the use of occlusive dressings.

Occlusion of the skin permits increased percutaneous absorption of topical corticosteroids. This increase results in increased levels of glucocorticoids in the blood or lymph. In general, the following types of occlusive dressings have been associated with augmented percutaneous absorption:

- tar bandages
- plastic wraps
- occlusive gauze bandages
- nonocclusive plastic film

Absorption increases proportionally with increasing duration of occlusion and intensity of inflammation. However, occlusive dressings are not required for effective topical corticosteroid therapy. If the occlusive dressing is removed unexpectedly or the patient is not compliant with the prescribed regimen, absorption of topical corticosteroids will decrease substantially.

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

Long-term animal studies have not been performed to evaluate the carcinogenic potential of Topicort® Topical Spray.

13.2 Reproduction

Reproduction studies were conducted in rats and rabbits. Desoximetasone was shown to be teratogenic in both species. However, if desoximetasone is administered systemically at levels lower than those achieved with topical application, it is unlikely that teratogenic effects will result from topical application. In overdose situations or accidental ingestion, topical corticosteroids may suppress the hypothalamic-pituitary-adrenal axis. This effect is reversible with discontinuation of treatment.

14 CLINICAL STUDIES

Two multi-center, randomized, double-blind, vehicle-controlled clinical trials were conducted in 239 subjects aged 15 years and older with moderate to severe plaque psoriasis of the body. In both trials, investigator subjects treated with Topicort® Topical Spray or vehicle spray to the affected areas twice daily for 4 weeks. Enrolled subjects had a minimum body surface area of involvement of 10% and a Physician's Global Assessment score (PGA) of 3 (mild) or 4 (moderate) at baseline.

Efficacy was assessed at Week 4 as the proportion of subjects who were considered a Clinical Success (clear or almost clear) at Week 4.

Table 2. Number of Subjects (%) with Clinical Success (clear or almost clear) at Week 4.

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Week 4</th>
</tr>
</thead>
<tbody>
<tr>
<td>Topicort®</td>
<td>11.2%</td>
</tr>
<tr>
<td>Vehicle</td>
<td>30.8%</td>
</tr>
</tbody>
</table>

15 HOW SUPPLIED/STORAGE AND HANDLING

15.1 How Supplied

15.1.1 Topicort® Topical Spray, 0.25% is a clear colorless liquid supplied in white, opaque bottles with opaque caps in the following sizes:

- 36 mL (N=401-531-3)
- 50 mL (N=415-531-3)
- 100 mL (N=30-531-5)
- 200 mL (N=547-531-5)

Store at controlled room temperature between 20°C to 25°C (68°F to 77°F), excursions permitted to 15°C to 30°C (59°F to 86°F). Protect from freezing. Do not store above 30°C (86°F).

16 PATIENT COUNSELING INFORMATION

See FDA-approved patient labeling (Patter in Information and Instructions for Use) before patients of the following:

- Use this medication as directed by the physician.
- Do not use this medication if you have a known allergy to this or any other corticosteroid.
- Do not use this medication if you are pregnant or nursing.
- Do not use this medication if you have certain medical conditions.
- Do not exceed the recommended dose.
- Do not use this medication longer than directed by the physician.
- Do not discontinue this medication suddenly.
- Do not share this medication with others.
- Do not use this medication if you have a known allergy to this or any other corticosteroid.
- Do not exceed the recommended dose.
- Do not discontinue this medication suddenly.
- Do not share this medication with others.

The patient information leaflet (Patter in Information and Instructions for Use) provides additional information for patients who are using this product. The patient information leaflet (Patter in Information and Instructions for Use) is available at www.TaroCanada.ca.

NRB by Taro Pharmaceuticals Inc., Brampton, Ontario, Canada L6T 1C1

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Print Line