DIPROLENE®
brand of augmented betamethasone dipropionate*
Lotion 0.05%
(potency expressed as betamethasone)
* Vehicle augments the penetration of the steroid.

For Dermatologic Use Only — Not for Ophthalmic Use

DESCRIPTION DIPROLENE® Lotion contains betamethasone dipropionate, USP, a synthetic adrenocorticosteroid, for dermatologic use. Betamethasone, an analog of prednisone, has a high degree of corticosteroid activity and a slight degree of mineralocorticoid activity. Betamethasone dipropionate is the 17,21-dipropionate ester of betamethasone.

Chemically, betamethasone dipropionate is 9-fluoro-11ß,17ß,21-trihydroxy-16a-methylpregna-1,4-diene-3,20-dione 17,21-dipropionate, with the empirical formula C₂₄H₂₃O₅, a molecular weight of 504.6, and the following structural formula:

\[
\text{HO} \quad \text{CH₃COCH₂CH₃} \quad \text{C} \quad \text{O} \quad \text{CH₃COCH₂CH₃} \quad \text{CH₃}
\]

Betamethasone dipropionate is a white to cream-colored, odorless crystalline powder, soluble in water.

Each gram of DIPROLENE® Lotion 0.05% contains: 0.643 mg betamethasone dipropionate, USP (equivalent to 0.5 mg betamethasone), in a lotion base of purified water, USP; isopropyl alcohol, USP (30%); hydroxypropyl cellulose, NF; propylene glycol, USP; sodium phosphate monobasic monohydrate; phosphoric acid, NF; used to adjust the pH to 4.5.

CLINICAL PHARMACOLOGY The corticosteroids are a class of compounds comprising steroid hormones secreted by the adrenal cortex and their synthetic analogs. In pharmacologic doses, corticosteroids are used primarily for their anti-inflammatory and/or immunosuppressive effects.

Topical corticosteroids, such as betamethasone dipropionate, are effective in the treatment of corticosteroid-responsive dermatoses primarily because of their anti-inflammatory, antipruritic, and vasoconstrictive actions. However, while the physiologic, pharmacologic, and clinical effects of the corticosteroids are well known, the exact mechanisms of their actions in each disease are uncertain. Betamethasone dipropionate, a corticosteroid, has been shown to have topical (dermatologic) and systemic pharmacologic and metabolic effects characteristic of this class of drugs.

Pharmacokinetics: The extent of percutaneous absorption of topical corticosteroids is determined by many factors including the vehicles used, the concentration of the active drug, and the integrity of the skin barrier. The percutaneous absorption of a vehicle augments the penetration of the steroid. Topical corticosteroids can be absorbed through normal intact skin. Inflammation and/or other disease processes in the skin may increase percutaneous absorption. Occlusive dressings substantially increase the percutaneous absorption of topical corticosteroids. (See DOSAGE AND ADMINISTRATION section.)

Topical corticosteroids can be absorbed through normal intact skin. After application to the skin, topically applied corticosteroids are metabolized by the liver and excreted in the urine and feces. Some of the topical corticosteroids and their metabolites are also excreted into the bile. DIPROLENE® Lotion was applied once daily at 7 mL per day for 21 days to diseased skin (in patients with scalp psoriasis) to study its effects on the hypothalamic-pituitary-adrenal (HPA) axis. In 2 out of 11 patients, the drug lowered plasma cortisol levels below normal limits. Adrenal suppression in these patients was transient and returned to normal within a week. In patients with scalp psoriasis, long-term animal studies have shown that 7 mL per day of corticosteroids such as DIPROLENE, use over large surface areas, prolonged use, and the addition of occlusive dressings. (See DOSAGE AND ADMINISTRATION section.)

Therefore, patients receiving large doses of a potent topical steroid applied to a large surface area 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.

Children may absorb proportionally larger amounts of topical corticosteroids and thus be more susceptible to systemic toxicity. (See PRECAUTIONS – Pediatric Use.)

NURSING MOTHERS: It is not known whether topical administration of corticosteroids can result in sufficient systemic absorption to produce detectable quantities in breast milk. Systemically administered corticosteroids are secreted into breast milk in amounts not likely to have a deleterious effect on the infant. Nevertheless, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

ADVERSE REACTIONS The overall incidence of drug-related adverse reactions in the DIPROLENE® Lotion clinical studies was 5%. The adverse reactions that were reported to be drug-related were possibly related to treatment with DIPROLENE® Lotion during controlled clinical studies involving 327 patients or normal volunteers were as follows: folliculitis occurred in 2%, burning and acneiform papules each occurred in 1%, and hypopigmentation and irritation each occurred in less than 1% of patients.

The following adverse reactions are also reported infrequently when topical corticosteroids are used as recommended. These reactions are listed in approximate decreasing order of occurrence: itching, dryness, hypopigmentation, perioral dermatitis, allergic contact dermatitis, maceration of the skin, secondary infection, skin atrophy, striae, miliaria, and maceration of the skin.

OVERDOSAGE Topically applied corticosteroids can be absorbed in sufficient amounts to produce detectable quantities in breast milk. Systemically administered corticosteroids can result in systemic effects. (See DOSAGE AND ADMINISTRATION section.)

DOSAGE AND ADMINISTRATION Apply a few drops of DIPROLENE® Lotion to the affected area once or twice daily and massage lightly until the lotion disappears. Treatment must be limited to 2 weeks, and amounts greater than 50 mL per week should not be used.

DIPROLENE® Lotion is not to be used with occlusive dressings.

HOW SUPPLIED DIPROLENE® Lotion 0.05% is supplied in 30-mL (29 g) and 50-mL (58 g) (NDC 0085-0821-01) and 50-mL (58 g) (NDC 0085-0822-02) plastic squeeze bottles, boxes of one. Store between 2° and 25°C (36° and 77°F).