ALCOMETASONE DIPROPIONATE LOTION 0.05%  

DESCRIPTION
Alcometasone Dipropionate Lotion, 0.05% contains alcometasone dipropionate (7α-chloro-11β,17α,21-trihydroxy-16α,17α-ethynylpregna-1,4-diene-3,20-dione 17β-dipropionate), a synthetic corticosteroid for topical dermatologic use. The corticosteroids constitute a class of primarily synthetic steroids used topically as anti-inflammatory and antipruritic agents.

Chemically, alcometasone dipropionate is C29H35CINO. It has the following structural formula:

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\text{Alcometasone dipropionate} = \text{C}_{29}\text{H}_{35}\text{CINO}
\]

Alcometasone dipropionate has the molecular weight at 521. It is a white powder, insoluble in water, slightly soluble in propylene glycol, and moderately soluble in hexylene glycol.

Each ml contains 0.5 mg of alcometasone dipropionate in a lotion consisting of isopropyl alcohol, cetyl alcohol, glyceryl monooleate, monobasic sodium phosphate, phosphoric acid, polysorbate 20, simethicone and propylene glycol.

CLINICAL PHARMACOLOGY
Like other topical corticosteroids, alcometasone dipropionate has anti-inflammatory, antipruritic, and vasoconstrictive properties. The mechanism of the anti-inflammatory activity of the topical steroids, in general, is unclear. However, corticosteroids are thought to act by the induction of phospholipase A2 inhibitory proteins, collectively called lipocortins. It is postulated that these proteins control the biosynthesis of potent mediators of inflammation such as prostaglandins and leukotrienes by inhibiting the release of their common precursor, arachidonic acid. Arachidonic acid is released from membrane phospholipids by phospholipase A2.

Pharmacokinetics: The extent of percutaneous absorption of topical corticosteroids is determined by many factors, including the vehicle and the integrity of the epidermal barrier. Occlusive dressings with hydrocarbons for up to 24 hours have not been demonstrated to increase penetration; however, occlusion of hydrocortisone for 96 hours markedly enhances penetration. Topical corticosteroids can be absorbed from normal intact skin. Inflammation and/or other disease processes in the skin may increase percutaneous absorption. A study utilizing a radiolabeled alcometasone dipropionate ointment formulation was performed to measure systemic absorption and excretion. Results indicated that approximately 3% of the steroid was absorbed during 8 hours of contact with intact skin of normal volunteers.

Studies performed with alcometasone dipropionate indicate that these products are in the low to medium range of potency as compared with other topical corticosteroids.

INDICATIONS AND USAGE
Alcometasone Dipropionate Lotion, 0.05% is a low to medium potency corticosteroid indicated for the relief of the inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses. Alcometasone Dipropionate Lotion, 0.05% may be used in pediatric patients 1 year of age or older, although the safety and efficacy of drug use for longer than 3 weeks have not been established (see PRECAUTIONS: Pediatric Use). Since the safety and efficacy of Alcometasone Dipropionate Lotion, 0.05% has not been established in pediatric patients below 1 year of age, their use in this age-group is not recommended.

CONTRAINDICATIONS
Alcometasone Dipropionate Lotion, 0.05% is contraindicated in those patients with a history of hypersensitivity to any of the components in these preparations.

PRECAUTIONS
General: Systemic absorption of topical corticosteroids can produce reversible hypothalamic-pituitary-adrenal (HPA) axis suppression with the potential for glucocorticosteroid insufficiency after withdrawal of treatment. Manifestations of HPA axis suppression include decreased plasma cortisol levels and suppression of adrenocorticotropic hormone (ACTH) gland stimulation. Patients applying a topical steroid to a large surface area or to areas under occlusion should be evaluated periodically for evidence of HPA axis suppression. This may be done by using the ACTH stimulation, A.M. plasma cortisol, and urinary free cortisol tests.

The effects of alcometasone dipropionate on the HPA axis have been evaluated. In one study, alcometasone dipropionate was applied to 30% of the body twice daily for 7 days, and occlusive dressings were used in selected patients each 12 hours or 24 hours daily. In another study, alcometasone dipropionate was applied to 80% of the body surface of normal subjects twice daily for 21 days with daily 12-hour periods of whole body occlusion. Average plasma and urinary cortisol levels have also been demonstrated to decrease in pediatric patients treated twice daily for 3 weeks without occlusion.

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 corticosteroid. Recovery of HPA axis function is generally prompt upon discontinuation of topical corticosteroids. Influenza, signs and symptoms of glucocorticosteroid insufficiency may occur, requiring supplemental systemic corticosteroids. For information on systemic supplementation, see prescribing information for those products.

Pediatric patients may be more susceptible to systemic toxicity from equivalent doses due to their larger skin surface area to body mass ratio (see PRECAUTIONS: Pediatric Use).

If irritation develops, Alcometasone Dipropionate Lotion, 0.05% should be discontinued and appropriate therapy instituted. Allergic contact dermatitis with corticosteroids is usually diagnosed by observing a failure to heal rather than noting a clinical exacerbation, as with most topical products not containing corticosteroids. Such an observation should be corroborated with appropriate diagnostic patch testing.

Information for Patients: 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. This medication should not be used for any disorder other than that for which it was prescribed.
3. The treated skin area should not be bandaged, otherwise covered or wrapped so as to be occlusive, unless directed by the physician.
4. Patients should report to their physician any signs of local adverse reactions.
5. Patients of pediatric patients should be advised not to use Alcometasone Dipropionate Lotion, 0.05% in the treatment of diaper dermatitis.

Alcometasone Dipropionate Lotion, 0.05% should not be applied in the diaper area, under occlusive dressings, or on skin folds.
Alclometasone Dipropionate Lotion, 0.05%

area as diapers or plastic pants may constitute occlusive dressing (see DOSAGE AND ADMINISTRATION). 6. This medication should not be used on the face, underarms, or groin areas unless directed by the physician.

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

ACTH stimulation test
A.M. plasma cortisol test
Urinary free cortic acid test

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

Pregnancy: Teratogenic Effects: Pregnancy Category C. Corticosteroids have been shown to be teratogenic in laboratory animals when administered systemically at relatively low dosage levels. Some corticosteroids have been shown to be teratogenic after dermal application in laboratory animals. There are no adequate and well-controlled studies in pregnant women. Alclometasone Dipropionate Lotion, 0.05% should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Nursing Mothers: Systemically administered corticosteroids appear in human milk and could suppress growth, interfere with endogenous corticosteroid production, or cause other unfavorable effects. It is not known whether topical administration of topical corticosteroids could result in sufficient systemic absorption to produce detectable quantities in human milk. Because many drugs are excreted in human milk, caution should be exercised when Alclometasone Dipropionate Lotion, 0.05% is administered to a nursing woman.

Pediatric Use: Systemically administered corticosteroids appear in human milk and could suppress growth, interfere with endogenous corticosteroid production, or cause other unfavorable effects. It is not known whether topical administration of topical corticosteroids could result in sufficient systemic absorption to produce detectable quantities in human milk. Because many drugs are excreted in human milk, caution should be exercised when Alclometasone Dipropionate Lotion, 0.05% is administered to a nursing woman.

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ADVERSE REACTIONS

The following local adverse reactions have been reported with Alclometasone Dipropionate Lotion, 0.05% in approximately 2% of patients: burning, itching, stinging, dryness, irritation, and popular rashes. The following additional local adverse reactions have been reported in frequency with topical corticosteroids, but may occur more frequently with the use of occlusive dressings. These reactions are listed in approximate decreasing order of occurrence: folliculitis, acneiform eruptions, hypopigmentation, perioral dermatitis, allergic contact dermatitis, secondary infection, skin atrophy, striae, and milliaria.

OVERDOSAGE

Topically applied Alclometasone Dipropionate Lotion, 0.05% can be absorbed in sufficient amounts to produce systemic effects (see PRECAUTIONS).

DOSAGE AND ADMINISTRATION

Apply a thin film of Alclometasone Dipropionate Lotion, 0.05% to the affected skin areas 2 or 3 times daily; massage gently until the medication disappears.

HOW SUPPLIED

Alclometasone Dipropionate Lotion, 0.05% is supplied in 2 oz and 4 oz bottles. Store between 2°C and 30°C (38°F and 86°F).
Alclometasone Dipropionate Lotion 0.05%
For dermatologic use only
Not for ophthalmic use

SHAKE WELL BEFORE USING. Store between 2°C and 30°C (36°F and 86°F). WARNING: Keep out of reach of children.

USUAL DOSAGE: Apply a thin film to the affected areas two or three times daily. See package insert for complete prescribing information.

Each ml contains 0.5 mg of alclometasone dipropionate in a lotion consisting of a lanolin alcohol, cetyl alcohol, glycerin monostearate, sorbitan monopalmitate, mineral oil, purified water, monobasic sodium phosphate, phosphoric acid, polyethylene 20, dimethicone and propylene glycol.

This product sealed for your protection. If the seal is broken or missing return to place of purchase.
SHAKE WELL BEFORE USING.
Store between 2°C and 30°C (36°F and 88°F).
WARNING: Keep out of reach of children.

USUAL DOSAGE: Apply a thin film to the affected areas two or three times daily.
See package insert for complete prescribing information.

Each ml contains 0.5 mg of alclometasone dipropionate in a lotion consisting of stearyl alcohol, cetyl alcohol, glyceryl monostearate, sorbitan monopalmitate, mineral oil, purified water, monobasic sodium phosphate, phosphoric acid, polysorbate 20, simethicone and propylene glycol.

This product sealed for your protection.
If the seal is broken or missing return to place of purchase.
Alclometasone Dipropionate Lotion 0.05% SHAKE WELL BEFORE USING.
Store between 2°C and 30°C (35°F and 86°F)
WARNING: Keep out of reach of children.
USUAL DOSAGE: Apply a thin film to the affected area two or three times daily. See package insert for complete prescribing information.
Each ml contains 0.5 mg of alclometasone dipropionate in a lotion consisting of isopropyl alcohol, cetyl alcohol, glycerin nonadecylate, sorbitan monostearate, mineral oil, purified water, monobasic sodium phosphate, phosphoric acid, polyethylene 20, simethicone and propylene glycol.
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NDC: 118 mL (4 fl oz)
SHAKE WELL BEFORE USING.
Store between 2°C and 30°C (36°F and 86°F).

WARNING: Keep out of reach of children.

USUAL DOSAGE: Apply a thin film to the affected areas two or three times daily.

See package insert for complete prescribing information.

Each ml contains 0.5 mg of Alclometasone dipropionate in a lotion consisting of stearyl alcohol, cetyl alcohol, glyceryl monostearate, sodium lauryl sulfate, purified water, monoclay sodium phosphate, phosphoric acid, polyalkylene glycol, simethicone and propylene glycol.

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