

Prescribing Information

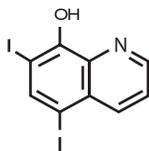
ALCORTIN A® gel

DESCRIPTION

Contents: Each gram of ALCORTIN A contains 2.0% (20 mg) Hydrocortisone Acetate, 1.0% (10 mg) Iodoquinol, and 1.0% (10 mg) Aloe Polysaccharides. Other Ingredients: Purified Water, Carbopol, Magnesium Aluminum Silicate, PPG-20 Methyl Glucose Ether, Aminomethyl Propanol, Propylene Glycol, Glycerine, Benzyl Alcohol, SD Alcohol 40 B, Biopeptide, Hydrochloric Acid, FD&C Blue #1, and D&C Yellow #10.

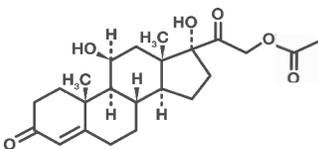
Iodoquinol

Iodoquinol is an antifungal and antibacterial agent. Chemically, Iodoquinol is [5,7-diiodo-8-quinolinol] with the molecular formula ($C_9H_5I_2NO$) and is represented by the following structural formula:



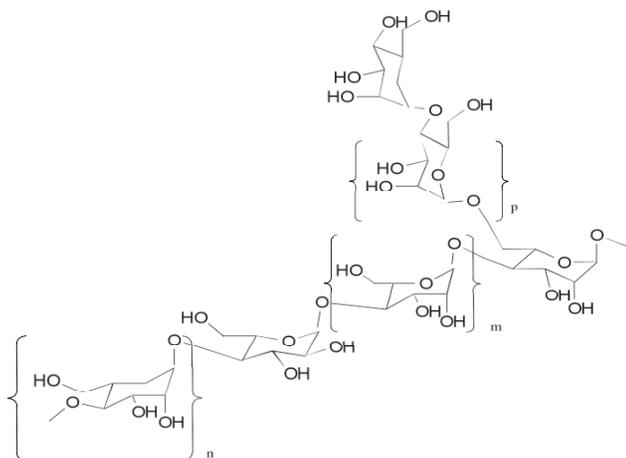
Hydrocortisone Acetate

Hydrocortisone Acetate is an anti-inflammatory and antipruritic agent. Chemically, Hydrocortisone Acetate is [Pregn-4-ene-3, 20-dione, 21-(acetyloxy)-11, 17-dihydroxy-, (11 β)-] with the molecular formula ($C_{23}H_{32}O_6$) and is represented by the following structural formula:



Aloe Polysaccharides

Aloe Polysaccharides are a concentrated, water soluble subcomponent of Aloe vera with a mono-sugar ratio of Man : Gal : Glc : 40 : 1.4 : 1.0, linkage of 1-4 β – linkage, O-Acetyl group of 25% of sugar units, and specific rotation of $[\alpha]_D = -3.98^\circ$ at 23.2 °C. Average molecular weight is 80,000 daltons. Chemically, Aloe Polysaccharides is represented by the following structural formula:



CLINICAL PHARMACOLOGY

Hydrocortisone Acetate has anti-inflammatory, antipruritic and vasoconstrictive properties. While the mechanism of anti-inflammatory activity is unclear, there is evidence to suggest that a recognizable correlation exists between vasoconstrictor potency and therapeutic efficacy in humans. Iodoquinol has both antifungal and antibacterial properties.

Pharmacokinetics

The extent of percutaneous absorption of topical steroids is determined by many factors including the vehicle, the integrity of the epidermal barrier and the use of occlusive dressings. Hydrocortisone Acetate can be absorbed from normal intact skin. Inflammation and/or other inflammatory disease processes in the skin increase percutaneous absorption. Occlusive dressings substantially increase the percutaneous absorption of topical corticosteroids. Once absorbed through the skin, Hydrocortisone Acetate is metabolized in the liver and most body tissue to hydrogenated and degraded forms such as tetrahydrocortisone and tetrahydrocortisol. These are excreted in the urine, mainly conjugated as glucuronides, together with a very small proportion of unchanged Hydrocortisone Acetate. There are no data available regarding the percutaneous absorption of Iodoquinol; however, following oral administration, 3-5% of the dose was recovered in the urine as a glucuronide.

INDICATIONS AND USAGE

Based on a review of a related drug by the National Research Council and subsequent FDA classification for that drug, the indications are as follows: "Possibly Effective: Contact or atopic dermatitis; impetiginized eczema; nummular eczema; endogenous chronic infectious dermatitis; stasis dermatitis; pyoderma; nuchal eczema and chronic eczematoid otitis externa; acne urticata; localized or disseminated neurodermatitis; lichen simplex chronicus; anogenital pruritus (vulvae, scroti, ani); folliculitis; bacterial dermatoses; mycotic dermatoses such as tinea (capitis, cruris, corporis, pedis); moniliasis; intertrigo. Final classification of the less-than-effective indications requires further investigation.

CONTRAINDICATIONS

ALCORTIN A is contraindicated in those patients with a history of hypersensitivity to Hydrocortisone Acetate, Iodoquinol, aloe vera, glycine, histidine, lysine, palmitic acid, or any other components of the preparation.

WARNINGS AND PRECAUTIONS

For external use only. Keep away from eyes. 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. If irritation develops, the use of ALCORTIN A should be discontinued and appropriate therapy instituted. Staining of the skin, hair, and fabrics may occur. Not intended for use on infants or under diapers or occlusive dressings. If extensive areas are treated or if the occlusive dressing technique is used, the possibility exists of increased systemic absorption of the corticosteroid, and suitable precautions should be taken. Children may absorb proportionally larger amounts of topical corticosteroids and thus be more susceptible to systemic toxicity. Parents of pediatric patients should be advised not to use tight-fitting diapers or plastic pants on a child being treated in the diaper area, as these garments may constitute occlusive dressings. Iodoquinol may be absorbed through the skin and interfere with thyroid function tests. If such tests are contemplated, wait at least one month after discontinuance of therapy to perform these tests. The ferric chloride test for phenylketonuria (PKU) can yield a false positive result if Iodoquinol is present in the diaper or urine. Prolonged use may result in overgrowth of non-susceptible organisms. Keep out of reach of children. Burning, itching, irritation, and dryness have been reported infrequently following the use of topical corticosteroids.

Carcinogenesis, Mutagenesis and Impairment

of Fertility: Long-term animal studies have not been performed to evaluate the carcinogenic potential of the effect on fertility of Hydrocortisone Acetate or Iodoquinol. In vitro studies to determine mutagenicity with Hydrocortisone Acetate have revealed negative results. Mutagenicity studies have not been performed with Iodoquinol.

Pregnancy Category C: Animal reproductive studies have not been conducted with ALCORTIN A. It is not known whether ALCORTIN A can cause fetal harm when administered to pregnant women or can affect reproductive capacity. ALCORTIN A should be given to pregnant women only if clearly needed.

Nursing Mothers: It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when ALCORTIN A is administered to a nursing woman.

Pediatric Use: Safety and effectiveness in pediatric patients under the age of 12 have not been established.

ADVERSE REACTIONS

The following local adverse reactions are reported infrequently with topical corticosteroids. These reactions are listed in an approximate decreasing order of occurrence: burning, itching, irritation, dryness, folliculitis, hypertrichosis, acneiform eruptions, hypopigmentation, perioral dermatitis, allergic contact dermatitis, maceration of the skin, secondary infections, skin atrophy, striae, and miliaria. Possible local adverse reactions associated with topical Iodoquinol include burning, itching, irritation, and dryness.

DOSAGE AND ADMINISTRATION

Apply to affected areas 3-4 times daily or as directed by a physician. Follow your physician's directions regarding length of treatment after symptoms resolve.

HOW SUPPLIED

NDC # 69646-705-15: 48 gram tube

NDC # 69646-705-13: 48 gram carton of 24-count of 2 gram gel individual packs

NDC # 69646-705-02: 2 gram gel individual pack, not intended for sale separately

NDC # 69646-705-08: 10-count carton of 2 gram gel sample packs - not for resale

NDC # 69646-705-03: 2 gram gel individual tube, not intended for sale separately

NDC # 69646-705-11: 10-count carton of 2 gram gel sample tubes - not for resale

Each 2 gram gel pack or tube contains multiple doses depending on the surface area treated.

STORAGE

Store at 20°C to 25°C (68°F to 77°F), excursions permitted between 15°C and 30°C (between 59°F and 86°F). Brief exposure to temperatures up to 40°C (104°F) may be tolerated provided the mean kinetic temperature does not exceed 25°C (77°F); however, such exposure should be minimized.

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