ALCORTIN A- hydrocortisone acetate, aloe vera leaf and iodoquinol gel
Primus Pharmaceuticals

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

ALCORTIN® A gel

Prescribing Information

DESCRIPTION

Each gram of Alcortin® A contains 2.0% (20 mg) Hydrocortisone Acetate and 1.0% (10 mg) Iodoquinol. Also contains 1.0% (10 mg) Aloe polysaccharide[1]. 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 FD&C Yellow # 10.

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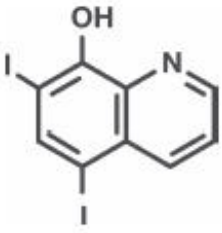
[1] U.S. Patents
#6,436,679; #6,271,214; #6,133,440; #5,708,038; patent pending

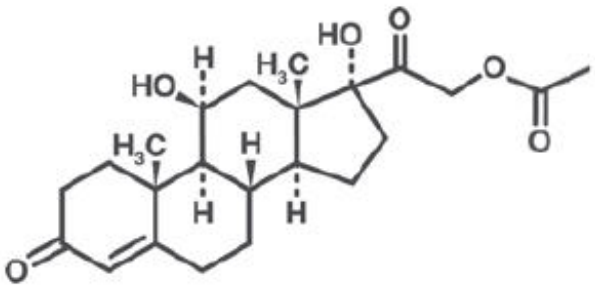
Iodoquinol

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, 11, 17, 21- trihydroxy-, (11β)-] with the molecular formula ($C_{21}H_{30}O_5$) and 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); monliasis; 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. 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 requiring appropriate therapy. Keep out of reach of children. Burning, itching, irritation and dryness have been reported infrequently following the use of topical corticosteroids.

Carcinogenesis, Mutagenisis and Impairment of Fertility

Long term animal studies have not been performed to evaluate the carcinogenic potential of the effect on fertility of hydrocortisone or iodoquinol. In vitro studies to determine mutagenicity with hydrocortisone 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.

DOSAGE AND ADMINISTRATION

Apply to affected area 3-4 times daily in accordance with physician's directions or as directed otherwise by a physician.

HOW SUPPLIED

FORM

48.0 gram carton of 24-count of 2.0 gram gel individual packs

NDC #68040-705-13

2.0 gram gel individual pack

NDC # 68040-705-02

10 count carton of 2.0 gram gel sample packs - not for resale

NDC # 68040-705-08

Each 2.0 gram gel pack contains multiple doses depending on the surface area treated.

STORAGE

Store at room temperature 15°-30°C (59°-86°F).

Keep tightly closed.

Rx only
www.alcortin.com

Distributed by:

Primus Pharmaceuticals, Inc.
Scottsdale, AZ 85251
www.primusrx.com

Manufactured by:
Sonar Products, Inc.
Carlstadt, NJ 07072

ISS. 1207 #00499

PRINCIPAL DISPLAY PANEL - 24 Pack Carton

NDC 68040-705-13
Rx only

Alcortin® A Gel
1% iodoquinol•2% hydrocortisone acetate
1% aloe polysaccharides

Anti-fungal • Anti-bacterial • Anti-inflammatory

24
PACK

Hygienic • Convenient
& Portable

Contains moisturizers • For dermatological use only

Biopeptide Aloe Complex™
Deeper Penetration
Patented Formula

Net Wt. 48.0 g (1.69 oz.) • **24 packs of 2.0g** (0.07 oz.) **each**

Each pack contains multiple doses
(depending on the surface area treated)

ALCORTIN A

hydrocortisone acetate, aloe vera leaf and iodoquinol gel

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:68040-705
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
HYDROCORTISONE ACETATE (UNII: 3X7931PO74) (HYDROCORTISONE - UNII:WI4X0X7BPJ)	HYDROCORTISONE ACETATE	20 mg in 1 g
ALOE VERA LEAF (UNII: ZY81Z83H0X) (ALOE VERA LEAF - UNII:ZY81Z83H0X)	ALOE VERA LEAF	10 mg in 1 g
Iodoquinol (UNII: 63W7IE88K8) (Iodoquinol - UNII:63W7IE88K8)	Iodoquinol	10 mg in 1 g

Product Characteristics			
Color	GREEN	**Score**	
Shape		**Size**	
Flavor		**Imprint Code**	
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:68040-705-13	24 in 1 BOX		
1	NDC:68040-705-02	1 g in 1 PACKET		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
UNAPPROVED OTHER		01/01/2010	

Labeler - Primus Pharmaceuticals (130834745)

Registrant - Sonar Products, Inc (104283945)

Establishment

Name	Address	ID/FEI	Business Operations
Sonar Products, Inc		104283945	MANUFACTURE

Revised: 10/2009 Primus Pharmaceuticals