ALCORTIN - 1% iodoquinol - 2% hydrocortisone 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 1% iodoquinol - 2% hydrocortisone with Aloe

Alcortin 2.0 g ucarton.jpg
NDC 68040-702-13 Rx only
Alcortin
Anti-fungal
Anti-bacterial
Anti-inflammatory
1% Iodoquinol 2% Hydrocortisone
See product literature for complete information.
TO OPEN A SINGLE PACK: Tear at notch along dotted line on front of package.
DOSAGE: Apply to affected area 3-4 times daily or as directed by your physician.
CONTENTS: This carton contains 24 single packs of 2.0 grams each of Alcortin gel. Each gram of Alcortin contains 2.0% (20 mg) Hydrocortisone and 1.0% (10 mg) Iodoquinol. Also contains 1.0% (10 mg) Aloe polysaccharide and 5.0% (50 mg) Biopeptide combination of Palmitoyl oligopeptide, Polyglyceryl methacrylate and Propylene glycol. Other ingredients: Aminomethyl propanol, Benzyl alcohol, Blue 1, Carbomer, Fragrance, Glycerin, Magnesium aluminum silicate, PPG-20 methyl glucose ether, Propylene glycol, Purified water, SO alcohol 40-B and Yellow 10.
WARNING: Keep out of reach of children. Not for use on infants or under diapers or occlusive dressings. For external use only. Avoid contact with eyes. May discolor skin, hair or fabrics.
www.alcortin.com
U.S. Patents #6,436,679; #6,271 ,214;
#6,133,440; #5,708,038; patent pending

Distributed by:
Primus Pharmaceuticals, Inc.
Scottsdale, AZ 85254
www.primusrx.com
Manufactured by:
Harmony Labs, Inc.
Landis, NC 28088
NDC 68040-702-13
Rx only
Alcortin
1% iodoquinol - 2% hydrocrtisone
Anti-fungal
Anti-bacterial
Anti-inflammatory
24 PACK
Allergy tested
Paraben free
Contains moisturizers
For dermatological use only
Each pack contains
multiple doses

(depending on the surface area treated)
NetWt 48.0g(1.69 oz)
24 packs of 2.0g(0.07 oz) each
NDC 68040-702-13
Alcortin
1% iodoquinol - 2% hydrocrtisone
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Anti-bacterial
Anti-inflammatory
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24 packs of 2.0g(0.07 oz) each
multiple doses
(depending on the surface area treated)

Alcortin 2 g packet.jpg
NDC 68040-702-02 Rx only
Alcortin gel 1% iodoquinol - 2% hydrocortisone with Aloe
Allergy tested - Paraben free
Contains moisturizers
For dermatological use only

Each pack contains multiple doses(depending upon the surface area treated)
NetWt. 2.0 g (0.07oz)
See product literature for complete information.
Dosage: Apply to affect area 3-4 times daily or as directed by your physician.
To Open: Tear at notch along dotted line on front of package.
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Insert

Prescribing Information
ALCORTINgel
DESCRIPTION
Each gram of Alcortin contains 2.0% (20 mg) Hydrocortisone and 1.0% (10 mg) Iodoquinol. Also contains 1.0% (10 mg) Aloe polysaccharide and 5.0% (50 mg) Biopeptide combination of Palmitoyloligopeptide, Polyglycerylmethacrylate and Propylene glycol. Other ingredients: Aminomethyl propanol, Benzyl alcohol, Blue 1, Carbomer, Fragrance, Glycerin, Magnesium aluminum silicate, PPG-20 methyl glucose ether, Propylene glycol, Purified water, SO alcohol 40-B and Yellow 10.
Iodoquinol
Iodoquinol is an antifungal and antibacterial

agent. Chemically, lodoquinol is [5,7-diiodo-8-quinolinol] with the molecular formula (C9HsI2NO)

Hydrocortisone

Hydrocortisone is an anti-inflammatory and antipruritic agent. Chemically, hydrocortisone is [Pregn-4-ene-3, 20-dione, 11, 17, 21- trihydroxy-, (11 B)-] with the molecular formula (C21H300s)

CLINICAL PHARMACOLOGY

Hydrocortisone 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. lodoquinol 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 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 throuah the skin. hvdrocortisone is tetrahydrocortisone and tetrahydrocortisol. These are excreted in the urine, mainly conjugated as glucuronides, together with a very small proportion of unchanged hydrocortisone. 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 is contraindicated in those patients with a history of hypersensitivity to hydrocortisone, 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 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. lodoquinol 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 res!Jlt 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 hydrocortinegative results. Mutagenicity studies have not been performed with iodoquinol.

Pregnancy Category C: Animal reproductive studies have not been conducted with Alcortin. It is not known whether Alcortin can cause fetal harm when administered to pregnant women or can affect reproductive capacity. Alcortin 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 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 NDC # 68040-702-13 .
48.0 gram carton of 24-count of 2.0 gram gel individual packs
FORM NDC # 68040-702-02
2.0 gram gel individual pack
FORM NDC # 68040-702-08
10 count carton of 2.0 gram gel sample packs - not for resale
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
U.S. Patents
#6,436,679; #6,271 ,214; #6,133,440;
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ALCORTIN

1% iodoquinol - 2% hydrocortisone gel

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:68040-702
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**

Hydrocortisone (UNII: WI4X0X7BPJ) (Hydrocortisone - UNII:WI4X0X7BPJ)	Hydrocortisone	2 g in 100 g
IODOQUINOL (UNII: 63W7IE88K8) (IODOQUINOL - UNII:63W7IE88K8)	IODOQUINOL	1 g in 100 g

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68040-702-08	64 in 1 BOX		
1		10 in 1 CARTON		
1	NDC:68040-702-02	2 g in 1 PACKET		
2	NDC:68040-702-13	12 in 1 BOX		
2		24 in 1 CARTON		
2		2 g in 1 PACKET		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		07/25/2003	

Labeler - Primus Pharmaceuticals (130834745)

Registrant - Harmony Labs, Inc. (105803274)

Establishment

Name	Address	ID/FEI	Business Operations
Harmony Labs, Inc.		105803274	manufacture, label, pack, repack, relabel

Revised: 4/2010 Primus Pharmaceuticals