HYDROCORTISONE IODOQUINOL- hydrocortisone and iodoquinol cream
Westminster Pharmaceuticals, LLC

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.

Hydrocortisone 1% - Iodoquinol 1% Cream

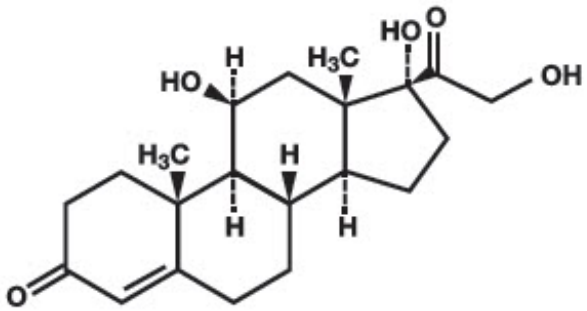
Rx Only

DESCRIPTION

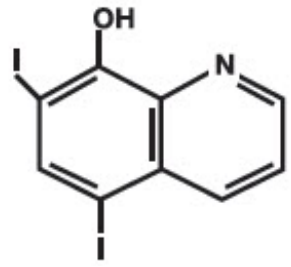
Each gram contains 10 mg of hydrocortisone and 10 mg of iodoquinol in a vehicle consisting of: cetyl alcohol, glycerin, glyceryl stearate SE, mineral oil, PEG-100 stearate, phenoxyethanol, purified water, stearyl alcohol, white petrolatum, xanthan gum.

Paraben Free.

Chemically, hydrocortisone 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:



and iodoquinol, 5, 7-diiodo-8-quinolinol ($C_9H_5I_2NO$) is represented by the following structural formula:



Hydrocortisone is an anti-inflammatory and antipruritic agent, while iodoquinol is an antifungal and antibacterial agent.

CLINICAL PHARMACOLOGY

Hydrocortisone has an 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 the therapeutic efficacy in humans Iodoquinol has both antifungal and antibacterial properties.

Pharmacokinetics

The extent of the 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 through the skin, hydrocortisone is metabolized in the liver and most body tissue to hydrogeneted 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. 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 glucuronide.

INDICATIONS

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

This product is contraindicated in persons with known or suspected hypersensitivity to any of the ingredients of the product.

WARNING

FOR EXTERNAL USE ONLY.

PRECAUTIONS

NOT FOR OPHTHALMIC USE.

KEEP OUT OF REACH OF CHILDREN.

Avoid contact with eyes, lips and mucous membranes.

Information for Patients

If irritation develops, the use of this product should be discontinued and appropriate therapy instituted. Staining of the skin, hair and fabrics may occur. Not intended for the use on infants or under diapers of 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.

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 on overgrowth of non-susceptible organisms requiring appropriate therapy.

Carcinogenesis, Mutagenesis and Impairment of Fertility

Long-term animal studies for carcinogenic potential have not been performed on this product to date. In vitro studies to determine mutagenicity with hydrocortisone have revealed negative results. Mutagenicity studies have not been performed with iodoquinol.

Pregnancy

Category C

Animal reproduction studies have not been conducted with this product. It is also not known whether this product can affect reproduction capacity or cause fetal harm when administered to a pregnant woman. This product should be used by a pregnant woman only if clearly needed or when potential benefits outweigh potential hazards to the fetus.

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 this product 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 to 4 times daily in accordance with physician's directions.

STORAGE

Store at 20°C to 25°C (68°F to 77°F), excursions permitted between 15°C to 30°C (between 59°F to 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. Keep container tightly closed.

NOTICE

Protect from freezing and excessive heat.

HOW SUPPLIED

1 oz. tubes, NDC 69367-286-01

To report a serious adverse event or obtain product information, call 1-844-221-7294.

Manufactured for:
Westminster Pharmaceuticals, LLC
Nashville, TN 37217

Rev. 01/23

PRINCIPAL DISPLAY PANEL - 28.4 g Tube Carton

NDC 69367-286-01
Rx Only

Hydrocortisone 1%-Iodoquinol 1% Cream

Westminster
Pharmaceuticals

Net Wt 1 oz (28.4 g)

HYDROCORTISONE IODOQUINOL

hydrocortisone and iodoquinol cream

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:69367-286
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
HYDROCORTISONE (UNII: W4X0X7BPJ) (HYDROCORTISONE - UNII:W4X0X7BPJ)	HYDROCORTISONE	10 mg in 1 g
IODOQUINOL (UNII: 63W7IE88K8) (IODOQUINOL - UNII:63W7IE88K8)	IODOQUINOL	10 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
CETYL ALCOHOL (UNII: 936JST6JCN)	
GLYCERYL STEARATE SE (UNII: FCZ5MH785I)	
MINERAL OIL (UNII: T5L8T28FGP)	
WATER (UNII: 059QF0KO0R)	
STEARYL ALCOHOL (UNII: 2KR89I4H1Y)	
XANTHAN GUM (UNII: TTV12P4NEE)	
GLYCERIN (UNII: PDC6A3C0OX)	
PEG-100 STEARATE (UNII: YD01N1999R)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
WHITE PETROLATUM (UNII: B6E5W8RQJ4)	

Product Characteristics

Color	YELLOW (Light yellow)	**Score**	
Shape		**Size**	
Flavor		**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69367-286-01	1 in 1 CARTON	09/17/2020	03/27/2026
1		28.4 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
UNAPPROVED DRUG OTHER		09/17/2020	03/27/2026

Labeler - Westminster Pharmaceuticals, LLC (079516651)

Revised: 9/2020 Westminster Pharmaceuticals, LLC