HYDROCORTISONE IODOQUINOL- hydrocortisone and iodoquinol cream
Syntenza 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.

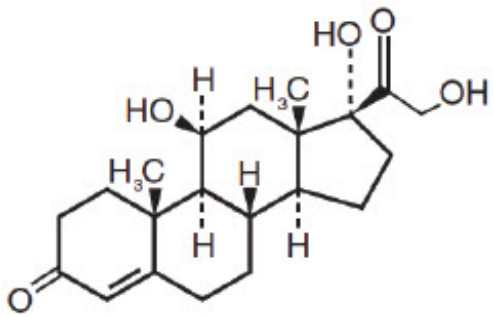
Hydrocortisone 1%-Iodoquinol 1% Cream

Rx Only

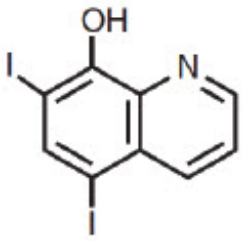
DESCRIPTION

Each gram of Hydrocortisone 1% – Iodoquinol 1% Cream contains 10 mg of hydrocortisone and 10 mg of iodoquinol in a greaseless base of cetyl alcohol, glyceryl monostearate SE, isopropyl myristate, lanolin alcohol, mineral oil, polyoxyl 40 stearate, polysorbate 20, polysorbate 60, propylene glycol, purified water, sorbic acid, and sorbitan monostearate. Paraben free.

Chemically, hydrocortisone is [Pregn-4-ene-3,20-dione, 11, 17, 21-trihydroxy-,(11ß)-] 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 structure:



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

CLINICAL PHARMACOLOGY

Hydrocortisone has anti-inflammatory, antipruritic and vasoconstrictor properties. The mechanism of anti-inflammatory activity is unclear. There is some evidence to suggest that a recognizable correlation exists between vasoconstrictor potency and therapeutic efficacy in man.

Iodoquinol has both antifungal and antibacterial properties.

Pharmacokinetics

The extent of percutaneous absorption of topical corticosteroids 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 tissues 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.

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; infantile 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

Hydrocortisone 1% – Iodoquinol 1% Cream is contraindicated in those patients with a history of hypersensitivity to hydrocortisone, iodoquinol or any other components of the preparation.

WARNINGS

FOR EXTERNAL USE ONLY. Keep away from eyes. Keep out of reach of children. Keep tube tightly closed.

If irritation develops, the use of Hydrocortisone 1% – Iodoquinol 1% Cream should be discontinued and appropriate therapy instituted. Staining of the skin, hair and fabrics may occur. If extensive areas are treated or if the occlusive 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.

PRECAUTIONS

Carcinogenesis, Mutagenesis, Impairment of Fertility

Long term animal studies have not been performed to evaluate the carcinogenic potential or 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 conducted with iodoquinol.

Pregnancy

Teratogenic Effects

Pregnancy Category C

Animal reproductive studies have not been conducted with Hydrocortisone 1% – Iodoquinol 1% Cream. It is not known whether Hydrocortisone 1% – Iodoquinol 1% Cream can cause fetal harm when administered to a pregnant woman or can affect reproductive capacity. Hydrocortisone 1% – Iodoquinol 1% Cream should be given to a pregnant woman 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 Hydrocortisone 1% – Iodoquinol 1% Cream is administered to a nursing woman.

Pediatric Use

Safety and effectiveness in pediatric patients below 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	Perioral dermatitis
Itching	Allergic contact dermatitis
Irritation	Maceration of the skin
Dryness	Secondary infection
Folliculitis	Skin atrophy
Hypertrichosis	Striae
Acneiform eruptions	Miliaria
Hypopigmentation	

DOSAGE AND ADMINISTRATION

Apply to affected area 3 to 4 times daily in accordance with physician's directions.

HOW SUPPLIED

Hydrocortisone 1% – Iodoquinol 1% Cream is available as follows: 1 oz. tube (NDC 72056-040-64)

STORAGE

Store at 20-25°C (68-77°F) [see USP Controlled Room Temperature]. Keep tightly closed.

Manufactured for:
Syntenza Pharmaceuticals LLC
Edina, MN 55436, USA

Rev. 06/18

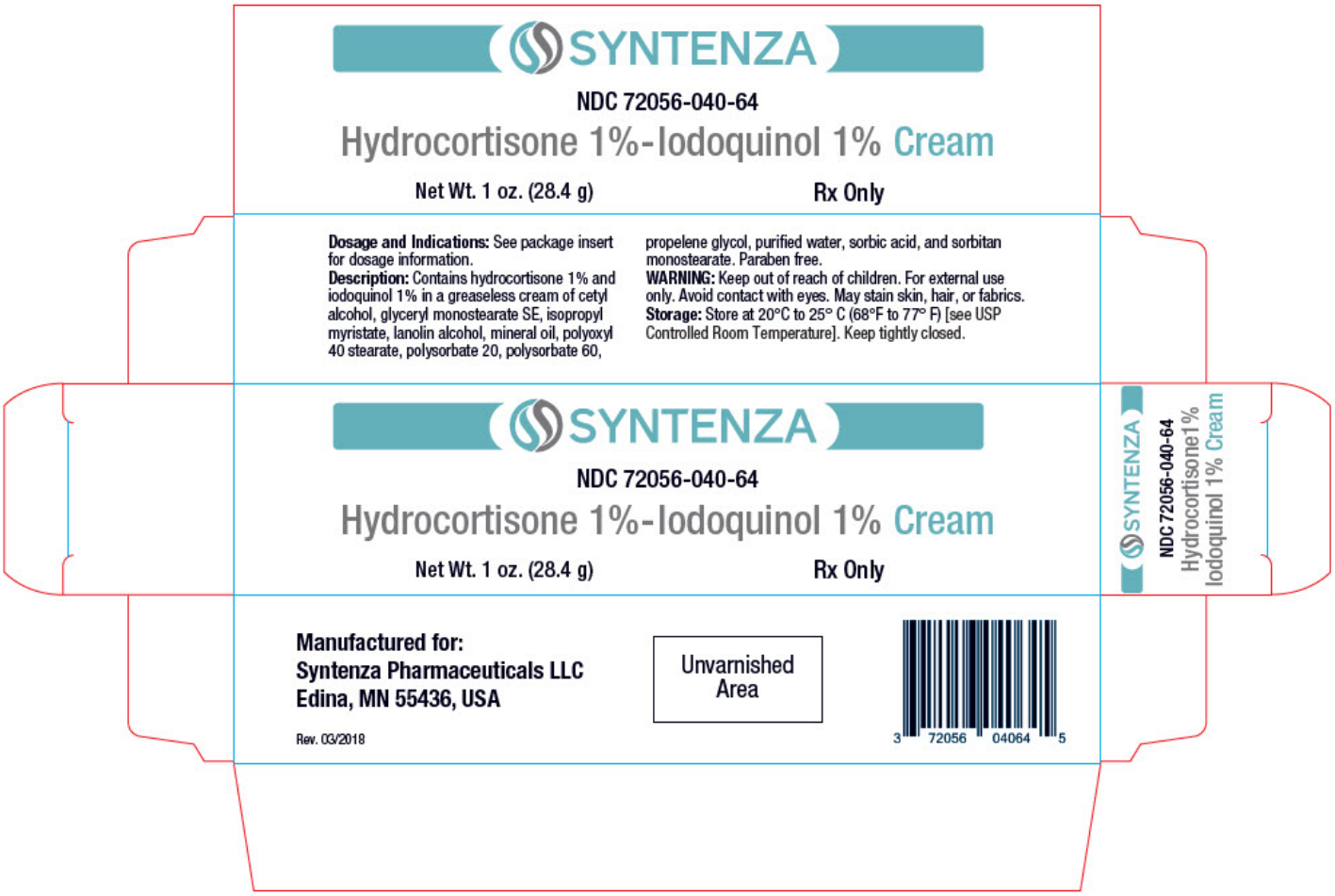
PRINCIPAL DISPLAY PANEL - 28.4 g Tube Carton

SYNTENZA

NDC 72056-040-64

Hydrocortisone 1%-Iodoquinol 1% Cream

Net Wt. 1 oz. (28.4 g)
Rx Only



HYDROCORTISONE IODOQUINOL

hydrocortisone and iodoquinol cream

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:72056-040
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
HYDROCORTISONE (UNII: WI4X0X7BPJ) (HYDROCORTISONE - UNII:WI4X0X7BPJ)	HYDROCORTISONE	10 mg in 1 g
IODOQUINOL (UNII: 63W7IE88K8) (IODOQUINOL - UNII:63W7IE88K8)	IODOQUINOL	10 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
Water (UNII: 059QF0KO0R)	
Cetyl Alcohol (UNII: 936JST6JCN)	
Polysorbate 20 (UNII: 7T1F30V5YH)	

Product Characteristics

Color	WHITE	**Score**	
Shape		**Size**	
Flavor		**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72056-040-64	1 in 1 CARTON	10/05/2018	
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		10/05/2018	

Labeler - Syntenza Pharmaceuticals LLC (080999747)

Revised: 5/2020 Syntenza Pharmaceuticals LLC