**IODOQUINOL HYDROCORTISONE ACETATE ALOE POLYSACCHARIDES- iodoquinol, hydrocortisone acetate, and aloe vera leaf gel**
**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.*

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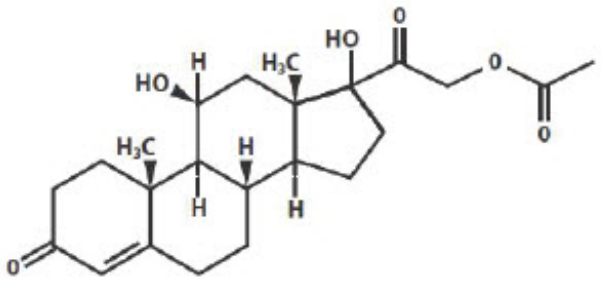
**Iodoquinol 1%-Hydrocortisone Acetate 2%**
**Aloe Polysaccharides 1% Gel**

Rx Only

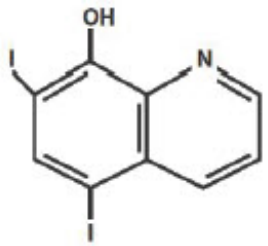
## DESCRIPTION

Each gram contains 20 mg of hydrocortisone acetate, 10 mg of iodoquinol and 10 mg of aloe polysaccharide in a vehicle consisting of: aminomethyl propanol, benzyl alcohol, blue 1, carbomer, glycerin, magnesium aluminum silicate, palmitoyl tripeptide-5, PPG-20 methyl glucose ether, purified water, propylene glycol, SD Alcohol 40B, yellow 10.

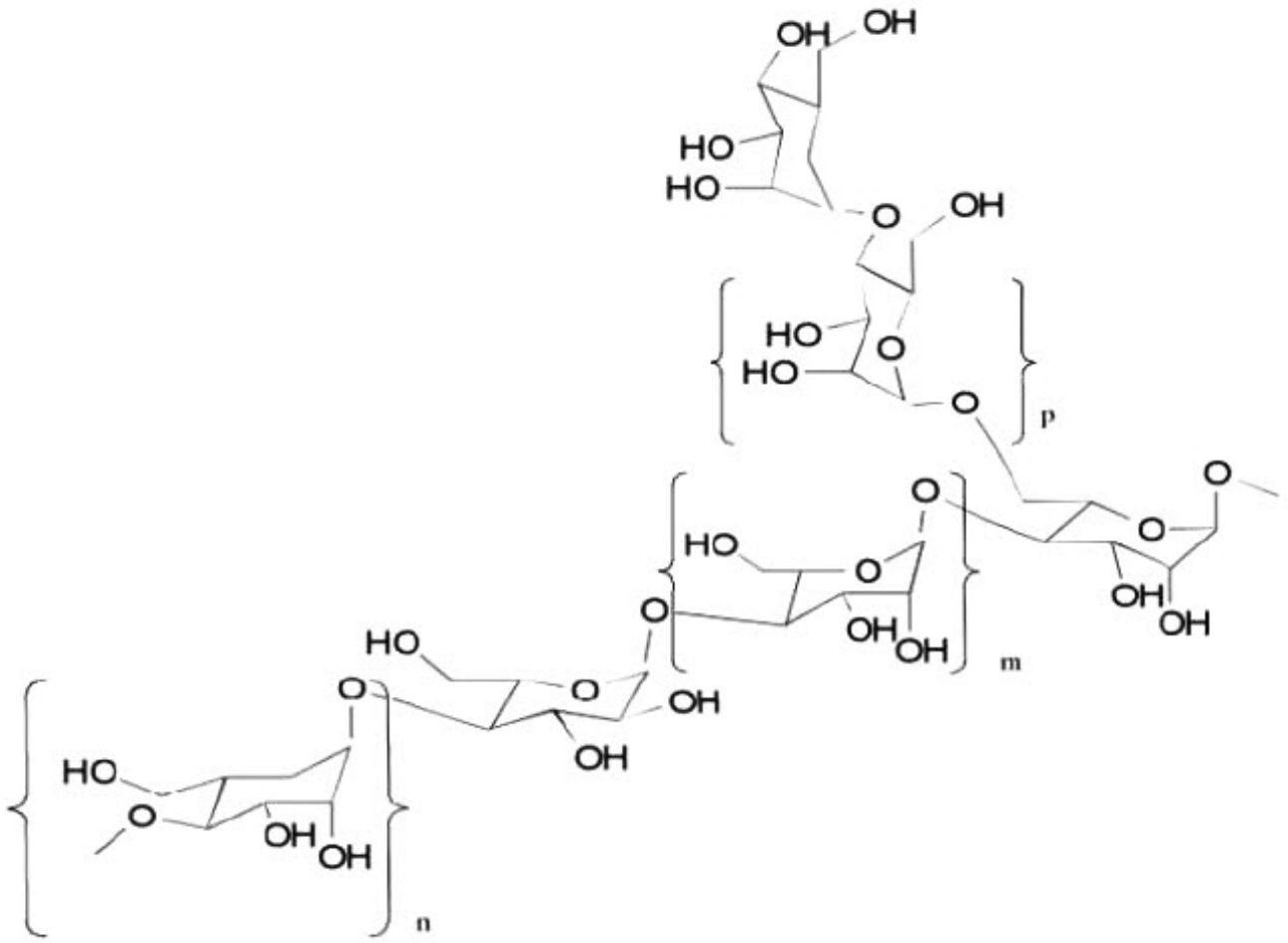
Hydrocortisone acetate is an anti-inflammatory and antipruritic agent. Chemically, hydrocortisone acetate is [Pregn-4-ene-3, 20-dione, 21-(acetyloxy)-11, 17-dihydroxy-, (11-β)-] with the molecular formula ($C_{23}H_{32}O_6$) and is represented by the following structural formula:




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:




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 ß - linkage, O-Acetyl group of 25% of sugar units, and specific rotation of $[\alpha]_D$= -3.98° 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

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

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

## WARNINGS

**KEEP OUT OF REACH OF CHILDREN.**

## PRECAUTIONS

**FOR EXTERNAL USE ONLY. NOT FOR OPHTHALMIC USE.** 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 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. 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 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(s) three to four times per day or as directed by a physician. Follow your physician's directions regarding length of treatment after symptoms resolve.

## 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.

**NOTICE:** Protect from freezing and excessive heat.

## HOW SUPPLIED

This product is supplied in the following size(s):

48 g Tube, NDC 72056-020-48

**Call your doctor about side effects. You may report side effects to FDA at 1-800-FDA-1088.**

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

**SYNTENZA**

Rev 06/18

## PRINCIPAL DISPLAY PANEL - 48 g Tube Carton

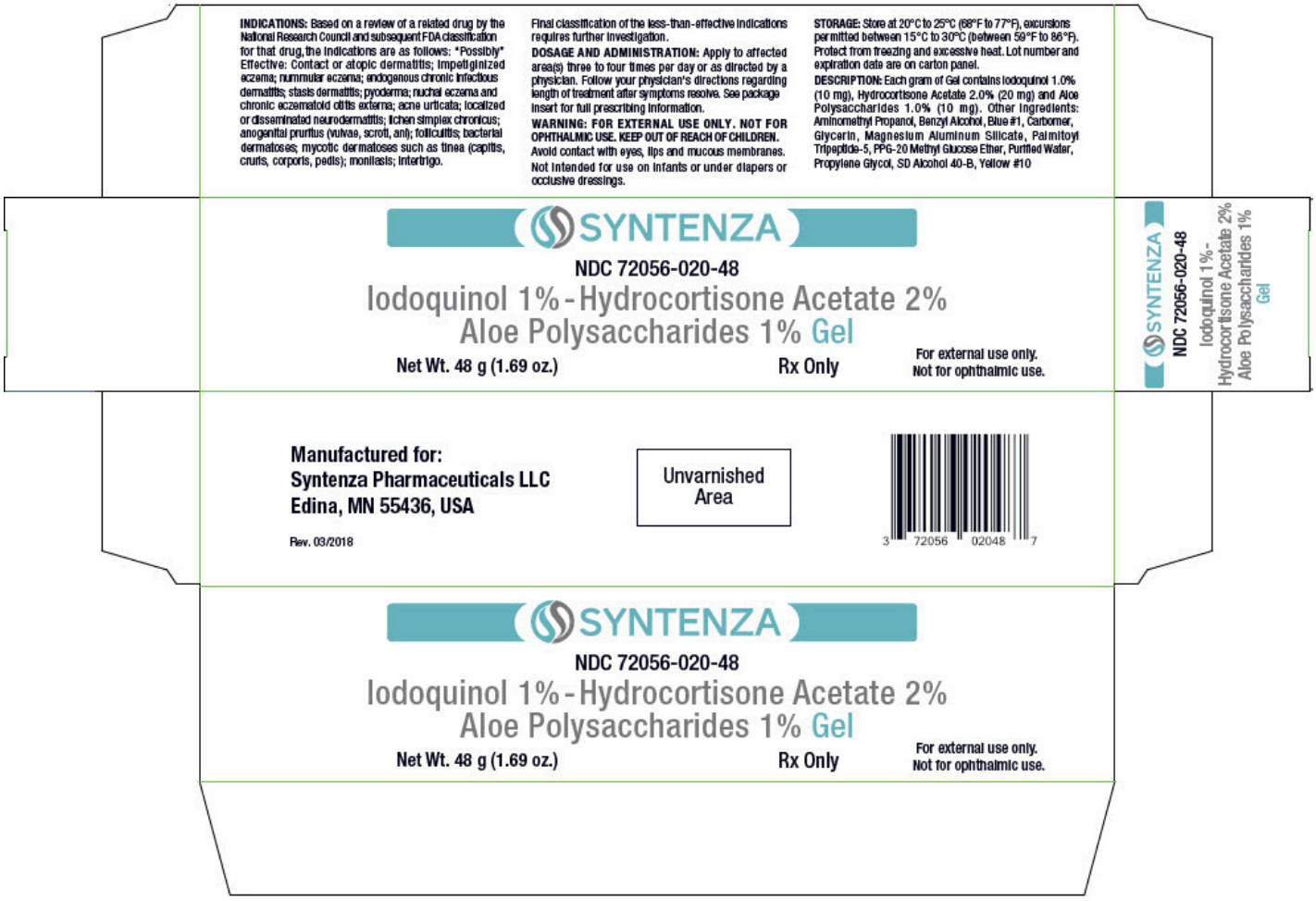
SYNTENZA

NDC 72056-020-48

Iodoquinol 1%-Hydrocortisone Acetate 2%
Aloe Polysaccharides 1% Gel

Net Wt. 48 g (1.69 oz.)
Rx Only

For external use only.
Not for ophthalmic use.




# IODOQUINOL HYDROCORTISONE ACETATE ALOE POLYSACCHARIDES

iodoquinol, hydrocortisone acetate, and aloe vera leaf gel

| Product Information | | | |
|---|---|---|---|
| **Product Type** | HUMAN PRESCRIPTION DRUG | **Item Code (Source)** | NDC:72056-020 |
| **Route of Administration** | TOPICAL | | |

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

| Product Characteristics | | | |
|---|---|---|---|
| **Color** | GREEN | **Score** | |
| **Shape** | | **Size** | |
| **Flavor** | | **Imprint Code** | |

| Contains | |
|---|---|

## Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|---|---|---|---|
| **1** | NDC:72056-020-48 | 1 in 1 CARTON | 11/01/2018 | |
| **1** | | 48 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 | | 11/01/2018 | |

## Labeler - Syntenza Pharmaceuticals LLC (080999747)

Revised: 5/2020 Syntenza Pharmaceuticals LLC