ALOQUIN- 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.

ALOQUIN® gel
(1.25% Iodoquinol and 1% Aloe Polysaccharides)

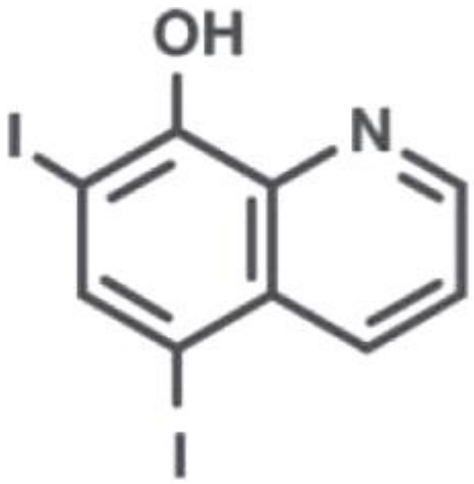
Prescribing Information

DESCRIPTION

Each gram of ALOQUIN contains 1.25% (12.5 mg) Iodoquinol and 1% (10mg) Aloe Polysaccharides. Other ingredients: Purified Water, Carbomer 980, Magnesium Aluminum Silicate, PEG-20 Methyl Glucose Ether, Aminomethyl Propanol 95, Biopeptide, Propylene Glycol, Glycerine, SDA Alcohol 40 B, Benzyl Alcohol, Trolamine, FD&C Blue #1 and D&C Yellow #10.

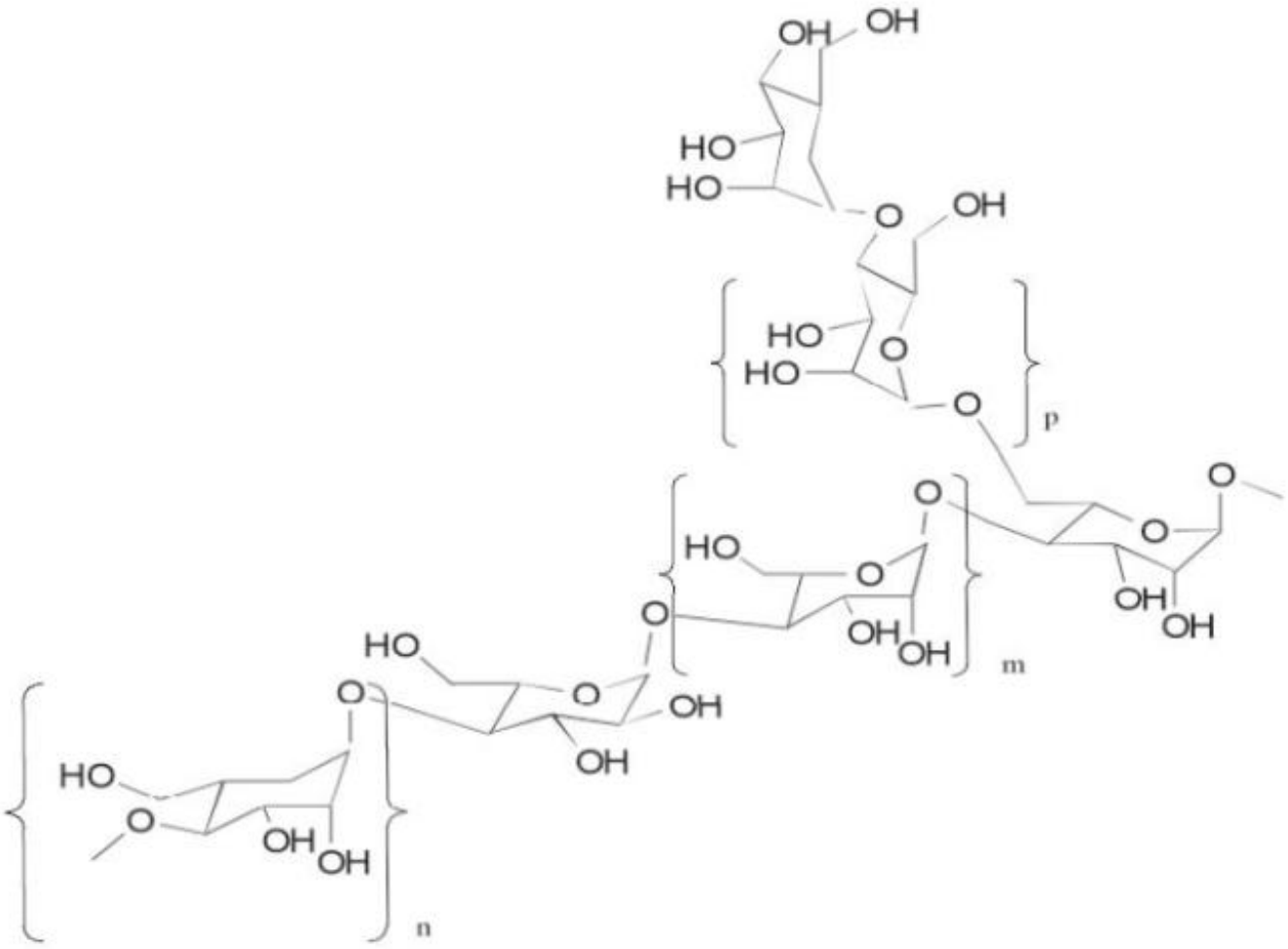
Iodoquinol

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:



Aloe Polysaccharide

The Aloe Polysaccharide in ALOQUIN is a patented mixture of acetylated mannan aloe polysaccharide. Each purified acetylated mannan polysaccharide of specific molecular weight range and average is composed of the same repeating subunits shown below (where m is mannose, n is galactose and p is glucose monomers):



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

ALOQUIN is contraindicated in those patients with a history of hypersensitivity to any components of the preparation.

WARNINGS AND PRECAUTIONS

For external use only. Keep away from eyes. If irritation develops, the use of ALOQUIN should be discontinued and appropriate therapy instituted. Some discoloration of the skin, hair and fabrics may occur, but can be removed with normal cleansing and laundry. Not intended for use on infants or under diapers or 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.

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 Iodoquinol. Mutagenicity studies have not been performed with Iodoquinol.

Pregnancy Category C

Animal reproductive studies have not been conducted with ALOQUIN. It is not known whether ALOQUIN can cause fetal harm when administered to pregnant women or can affect reproductive capacity. ALOQUIN 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 ALOQUIN 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

Adverse reactions from topical use of ALOQUIN is expected to be low when used as directed, due to low concentration of Iodoquinol present in this topical gel.

To achieve the equivalent of a common daily oral dose of nearly 2,000 mg Iodoquinol, one will need to use more than 2 full tubes of 60 g ALOQUIN in a single application. Adverse reactions from oral form of Iodoquinol (nearly 2,000 mg daily) have been reported: various forms of skin eruptions, hives, itching, nausea, vomiting, abdominal cramps, diarrhea, anusitis, fever, chills, headache, vertigo and enlargement of thyroid.

DOSAGE AND ADMINISTRATION

Apply to affected areas 3-4 times daily or as directed by a physician. Follow your physician's directions regarding length of treatment after symptoms resolve.

HOW SUPPLIED

NDC # 68040-706-16	60 gram gel tube
NDC # 68040-706-01	1 gram gel individual pack
NDC # 68040-706-08	10-count carton of 1 gram gel sample packs - not for resale

Each 1 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.aloquin.com

Manufactured for:

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

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

U.S. Patents #6,436,679; #6,271,214; #6,133,440; #5,925,357; #5,902,796; #5,708,038; #5,703,060; #5,468,737; other patents pending.

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PRINCIPAL DISPLAY PANEL - 60g Carton

NDC 68040-706-16

AloQuin™ GEL

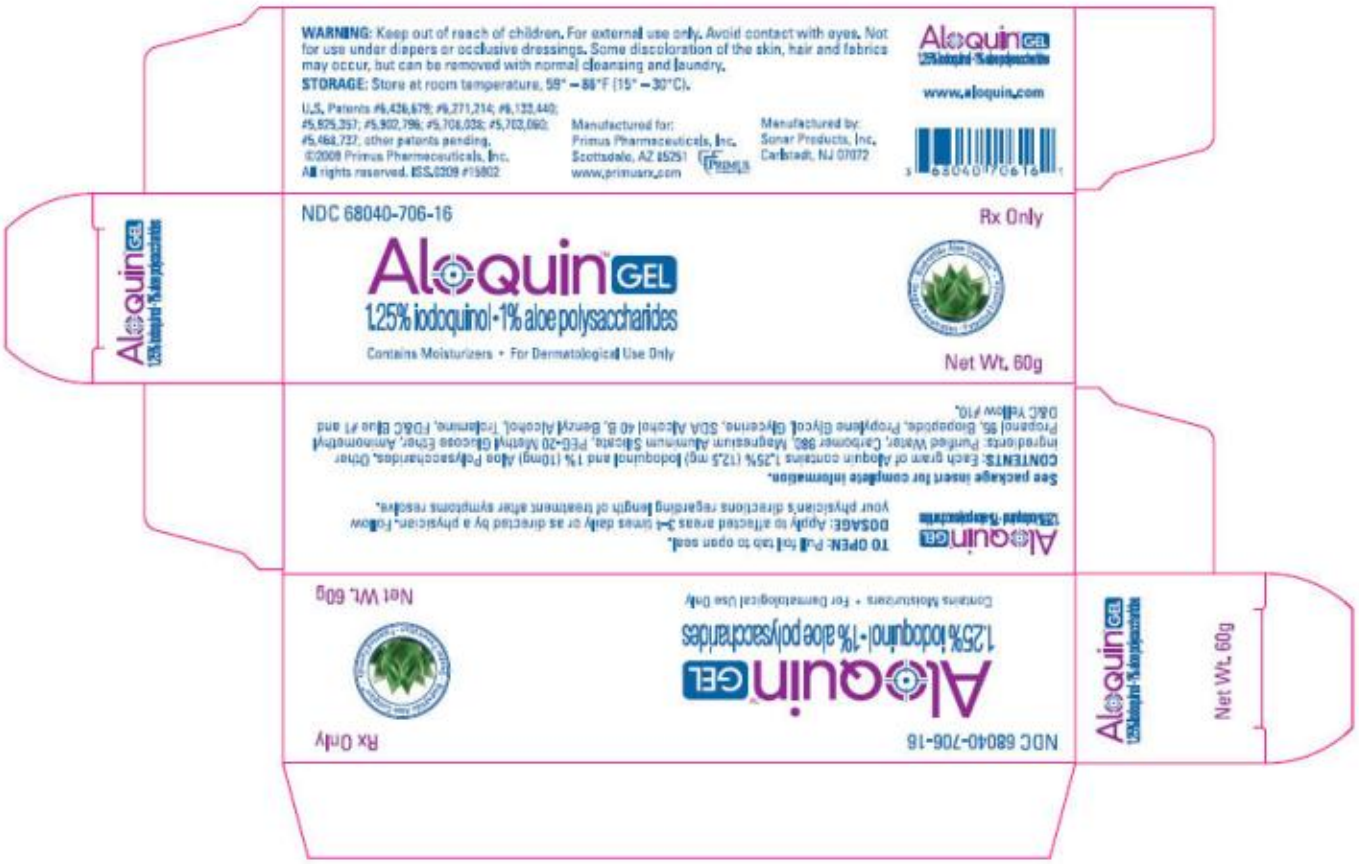
1.25% iodoquinol • 1% aloe polysaccharides

Contains Moisturizers • For Dermatological Use Only

Rx Only

Biopeptide Aloe Complex™
Deeper Penetration • Patented Formula

Net Wt. 60g



ALOQUIN

aloe vera leaf and iodoquinol gel

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:68040-706
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
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	12.5 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:68040-706-16	1 in 1 BOX		
1		60 g in 1 TUBE		
2	NDC:68040-706-01	1 g in 1 PACKET		
3	NDC:68040-706-08	10 in 1 BOX		
3		1 g in 1 PACKET		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Unapproved other		07/06/2009	

Labeler - Primus Pharmaceuticals (130834745)

Establishment

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

Revised: 10/2009

Primus Pharmaceuticals