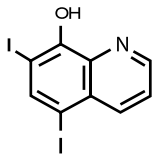
Prescribing Information

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

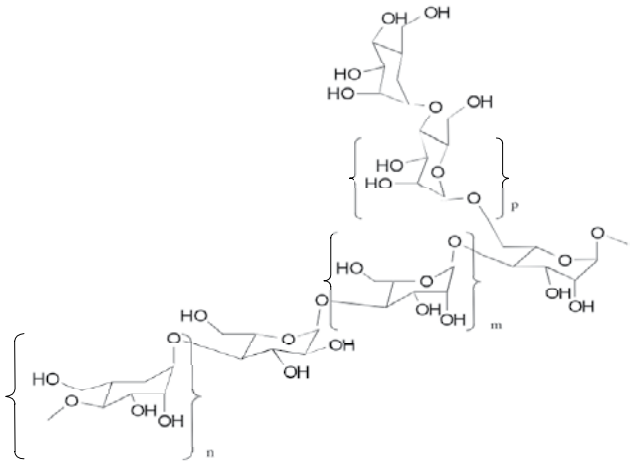
DESCRIPTION

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 mixture with average molecular weights of 80 and 1300 kDa (CAS 89191-46-8). 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 over-growth 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 # 69646-706-16……60 gram gel tube
NDC # 69646-706-01……1 gram gel individual pack
NDC # 69646-706-08……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 20°C to 25°C (68°F to 77°F), excursions permitted between 15°C and 30°C (between 59°F and 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.

Distributed by:
Novum Pharma, LLC.
Chicago, IL 60654

NOVUM PHARMA

15905-0217