FUNGIZYL AC- dimethyl sulfoxide 2%, miconazole nitrate 2% cream
Puretek Corporation

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.

Fungizyl AC

DESCRIPTION:

Fungizyl AC™ is a topical antifungal formulation that combines Dimethyl Sulfoxide (DMSO) and Miconazole Nitrate with a mixture of emollients and essential oils. The formulation is designed to provide effective antifungal activity while also soothing and moisturizing the skin.

Each gram of **Fungizyl AC™** contains 20 mg of Dimethyl Sulfoxide and 20 mg of Miconazole Nitrate in a vehicle with Aleurites Moluccana (Kukui) Seed Oil, Aqua (Purified Water), Butylene Glycol, Caprylyl Glycol, Carthamus Tinctorius (Safflower) Seed Oil, Cety Alcohol, Cetyl Phosphate, Chlorphenesin, Dimethicone, Dimethicone Crosspolymer, Disodium EDTA, DL-Alpha-Tocopheryl Acetate, GenRx® Complex (Proprietary Blend), Glycerin, Glyceryl Stearate, PEG-100 Stearate, Pentylene Glycol, Phenoxyethanol, Sodium Hydroxide, and Stearyl Alcohol.

INDICATIONS:

Fungizyl AC™ is indicated for the treatment of fungal infections of the skin, including athlete's foot, jock itch, and ringworm. It also helps with superficial skin infections caused by Candida species. Dimethyl Sulfoxide (DMSO) enhances the penetration of Miconazole Nitrate through the skin, improving antifungal effectiveness.

MECHANISM OF ACTION:

Miconazole Nitrate: An antifungal agent that inhibits the biosynthesis of ergosterol, a key component of fungal cell membranes, resulting in increased cell permeability and leakage of cellular contents. **Dimethyl Sulfoxide (DMSO):** A penetration enhancer that increases the absorption of Miconazole Nitrate through the skin, allowing for deeper antifungal action.

PHARMACOKINETICS:

When applied topically, miconazole nitrate exhibits minimal systemic absorption. Most of the drug remains on the skin surface and provides localized antifungal activity.

CONTRAINDICATIONS:

This product is contraindicated in patients with known hypersensitivity to any of its

ingredients.

WARNINGS:

For external use only. Not for ophthalmic use.

PRECAUTIONS:

Allergic Reactions: Hypersensitivity reactions, including severe allergic contact dermatitis and anaphylactic reactions, have been reported with miconazole use. Discontinue use immediately if signs of hypersensitivity occur.

USE IN PREGNANCY:

Category C: There are no adequate and well-controlled studies of miconazole nitrate or DMSO use in pregnant women. It should be used during pregnancy 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 this drug is administered to a nursing mother.

PEDIATRIC USE:

Safety and efficacy in children have not been established.

ADVERSE REACTIONS:

The most common side effects reported during the use of miconazole-containing products are local irritation, burning, stinging, redness, or swelling at the application site.

DOSAGE AND ADMINISTRATION:

• Clean the affected area and dry thoroughly. Apply a thin layer of **Fungizyl AC™** over the affected area twice daily (morning and evening) or as directed by a licensed healthcare practitioner. • Continue treatment for at least 2 weeks, even if symptoms improve, to reduce the likelihood of recurrence. • If there is no improvement after 4 weeks of treatment, discontinue use and consult a licensed healthcare practitioner.

HOW SUPPLIED:

Fungizyl AC™ is supplied in a 3 oz. (85 g) tube with a CRC cap (NDC 59088-206-07).

KEEP THIS AND ALL MEDICATIONS OUT OF REACH OF CHILDREN. Store at 20º-25ºC (68º-77ºF) [see USP Controlled Room Temperature]. Protect from freezing and

excessive heat. Keep container tightly closed.

LABEL

Manufactured by:
PureTek Corporation
Panorama City, CA 91402
For questions or information
call toll-free: **877-921-7873.**

FUNGIZYL AC

dimethyl sulfoxide 2%, miconazole nitrate 2% cream

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:59088-206
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
MICONAZOLE NITRATE (UNII: VW4H1CYW1K) (MICONAZOLE - UNII:7NNO0D7S5M)	MICONAZOLE NITRATE	20 mg in 1 g
DIMETHYL SULFOXIDE (UNII: YOW8V9698H) (DIMETHYL SULFOXIDE - UNII:YOW8V9698H)	DIMETHYL SULFOXIDE	20 mg in 1 g

Inactive Ingredients	
Ingredient Name	**Strength**
STEARYL ALCOHOL (UNII: 2KR89I4H1Y)	
DIMETHICONE CROSSPOLYMER (UNII: UF7620L1W6)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
SAFFLOWER OIL (UNII: 65UEH262IS)	

KUKUI NUT OIL (UNII: TP11QR7B8R)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
CETYL PHOSPHATE (UNII: VT07D6X67O)	
PENTYLENE GLYCOL (UNII: 50C1307PZG)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)	
GLYCERIN (UNII: PDC6A3C0OX)	
GLYCERYL 1-STEARATE (UNII: 258491E1RZ)	
PEG-100 STEARATE (UNII: YD01N1999R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59088-206-07	85 g in 1 TUBE; Type 0: Not a Combination Product	12/04/2024	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		12/04/2024	

Labeler - Puretek Corporation (785961046)

Establishment

Name	Address	ID/FEI	Business Operations
Puretek Corporation		785961046	manufacture(59088-206)

Revised: 10/2024 Puretek Corporation