FUNGIZYL AL- dimethyl sulfoxide 2% and miconazole 2% liquid liquid
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 AL

DESCRIPTION:

Fungizyl AL™ 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.

Fungizyl AL™ contains 20 mg of Dimethyl Sulfoxide and 20 mg of Miconazole Nitrate per gram in an anhydrous vehicle with Argania
Spinosa (Argan) Kernel Oil, Benzyl Alcohol, C13-14 Isoparaffin, DL-Alpha-Tocopheryl Acetate, Ethoxydiglycol, Eucalyptus Globulus (Eucalyptus) Leaf Oil, Glycerin, Laureth-7, Lavandula Angustifolia (Lavender) Oil, Melaleuca Alternifolia (Tea Tree) Leaf Oil, PEG-8, Polyacrylamide and Propylene Glycol.

INDICATIONS:

Fungizyl AL™ 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 AL™** 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.

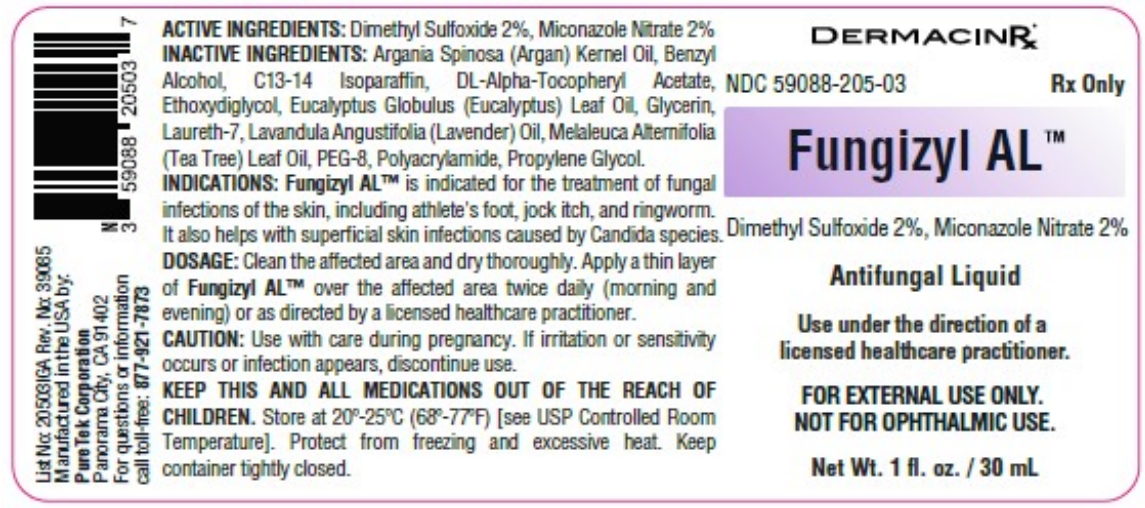
• If there is no improvement after 4 weeks of treatment, discontinue use and consult a licensed healthcare practitioner.

HOW SUPPLIED:

Fungizyl AL™ is supplied in a 1 fl. oz. / 30 mL glass bottle with a screw cap fitted with a brush applicator (NDC 59088-205-03).

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

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



FUNGIZYL AL

dimethyl sulfoxide 2% and miconazole 2% liquid liquid

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:59088-205
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
MICONAZOLE NITRATE (UNII: VW4H1CYW1K) (MICONAZOLE - UNII:7NNO0D7S5M)	MICONAZOLE NITRATE	2 g in 100 mL
DIMETHYL SULFOXIDE (UNII: YOW8V9698H) (DIMETHYL SULFOXIDE - UNII:YOW8V9698H)	DIMETHYL SULFOXIDE	2 g in 100 mL

Inactive Ingredients	
Ingredient Name	**Strength**
GLYCERIN (UNII: PDC6A3C0OX)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
EUCALYPTUS OIL (UNII: 2R04ONI662)	
ARGAN OIL (UNII: 4V59G5UW9X)	
LAURETH-7 (UNII: Z95S6G8201)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	

LAVENDER OIL (UNII: ZBP1YXW0H8)	
C13-14 ISOPARAFFIN (UNII: E4F12ROE70)	
MELALEUCA ALTERNIFOLIA (TEA TREE) LEAF OIL (UNII: VIF565UC2G)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
DIETHYLENE GLYCOL MONOETHYL ETHER (UNII: A1A1I8X02B)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59088-205-03	30 mL in 1 BOTTLE, GLASS; Type 0: Not a Combination Product	02/26/2025	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		02/26/2025	

Labeler - Puretek Corporation (785961046)

Establishment

Name	Address	ID/FEI	Business Operations
Puretek Corporation		785961046	manufacture(59088-205)

Revised: 2/2025 Puretek Corporation