# FUNGUS MASTER ANTIFUNGAL TREATMENT- miconazole nitrate lotion Ebanel Laboratories, Inc

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### **Fungus Master Antifungal Treatment**

#### **DRUG FACTS**

### **Active Ingredient**

Miconazole Nitrate 2%

### **Purpose**

**Antifungal** 

#### Uses

- Proven clinically effective in the treatment of most athlete's foot(Tinea Pedis), jock itch(Tinea Cruris) and ringworm(Tinea Corporis).
- For effective relief of itching, scaling, cracking, burning, redness, Soreness, irritation, discomfort, itchy, scaly skin between the toes, and chafing associated with jock itch.

### Warnings

- Do not use on children under 2 years of age.
- For external use only.
- Avoid contact with the eyes.
- If irritation occurs or if there is no improvement within 4 weeks (for athlete's foot and ringworm) or within 2 weeks (for jock itch), discontinue use and consult a doctor.

### Keep out of reach of children.

If swallowed, get medical help or contact a poison control center right away.

### **Directions**

Wash the affected area and dry thoroughly. Apply a thin layer of the product over affected area twice daily (morning and night) or as directed by a doctor. Supervise children in the use of this product. For athlete's foot: Pay special attention to spaces between the toes; wear well-fitting, ventilated shoes, and change shoes and socks at least once daily. For athlete's foot and ringworm use daily for 4 weeks; for jock itch, use daily for 2 weeks. If condition persists longer, consult a doctor. This product is not effective on the scalp or nails. Store at 15-30°C (59-86°F)

#### Other Information

Functional ingredients used in this formula have been shown to improve the appearance of thickened, discolored, and unhealthylooking feet caused by dermatophytic fungi. Urea has been shown to thin, soften, and act as penetrating agent on skin. Undecylenic acid is effective as an emulsifier, cleanser, and preservative.

### **Inactive Ingredients**

Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Arginine, Ascorbyl Palmitate, Carthamus Tinctorius (Safflower) Seed Oil, Cetearyl Alcohol, Cinnamomum Zeylanicum Leaf Oil, Citrus Aurantium Dulcis (Orange) Peel Oil, Cocos Nucifera (Coconut) Oil, Cymbopogon Flexuosus Oil, Dimethyl Isosorbide, Dodecane, Eucalyptus Globulus Leaf Oil, Eugenia Caryophyllus (Clove) Flower Oil, Glycerin, Lavandula Angustifolia (Lavender) Flower Oil, Leptospermum Scoparium Branch/Leaf Oil, Melaleuca Alternifolia (Tea Tree) Leaf Oil, Mentha Piperita (Peppermint) Oil, Oreganum Vulgare Leaf Oil, Panthenol, PEG-12 Dimethicone, PEG-40 Hydrogenated Castor Oil, PEG-8 Dilaurate, Persea Gratissima (Avocado) Oil, Phenoxyethanol, Phospholipids, Polysorbate 20, Polysorbate 60, PPG-26-Buteth-26, Punica Granatum Seed Extract, Retinyl Palmitate, Salicylic Acid, Santalum Spicatum Seed Oil, Simmondsia Chinensis (Jojoba) Seed Oil, Sodium Benzoate, Sodium Bicarbonate, Tocopheryl Acetate, Undecylenic Acid, Inact ive Ingredients Urea, Water

### **Package Labeling:**



#### **DRUG FACTS** (Continued)

- Avoid contact with the
- If irritation occurs or if there is no improvement within 4 weeks for the treatment of athlete's foot and ringworm, or 2 weeks for the treatment of jock itch, discontinue use and consult a doctor.

#### **Directions**

Clean the affected area and dry thoroughly. Apply a thin layer of the product over affected area twice daily (morning and night) or as directed by a doctor. Supervise children in the use of this product. For athlete's foot: Pay special attention to spaces between

#### DRUG FACTS (Continued)

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#### Other Information

Keep away from direct sunlight or heat. Store at room temperature 15°-30°C (59°-86°F). Keep out of reach of children. Do not use this product if seal is broken or missing.

Inactive Ingredients Acrylates/C10-30 Alkyl

#### DRUG FACTS (Continued)

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#### DRUG FACTS (Continued)

(Peppermint) Oil, Origanum Vulgare Leaf Oil, Panthenol, PEG-12 Dimethicone, PEG-40 Hydrogenated Castor Oil, PEG-8 Dilaurate, Persea Gratissima (Avocado) Oil, Phenoxyethanol, Phospholipids, Polysorbate 20. Polysorbate 60, PPG-26-Buteth-26.Punica Granatum Seed Extract, Retinyl Palmitate, Salicylic Acid, Santalum Spicatum Seed Oil, Simmondsia Chinensis (Jojoba) Seed Oil, Sodium Benzoate, Sodium Bicarbonate, Tocopheryl Acetate, Undecylenic Acid, Urea, Water



@EbanelSkincare 

- Manufactured in USA for Ebanel Laboratories, Inc.
- 1400 W. Lambert Rd., Suite D Brea, CA 92821 | www.ebanel.com

Athlete's Foot Ringworm, Jock Itch

#### 2% MICONAZOLE

Enhanced with Inactive Ingre-Undecylenic Acid, Herbal Oils

2.0 fl.oz e 59 mL

#### **DRUG FACTS**

#### Active Ingredient Purpose Miconazole Nitrate 2%.. Antifungal

#### Uses

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- corporis).

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#### Warnings

Clinically-Proven

- Do not use on children under 2 years of age unless directed by a doctor.
- For external use only.

#### DRUG FACTS (Continued)

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DRUG FACTS (Continued) (Peppermint) Oil, Origanum Vulgare Leaf Oil, Panthenol, PEG-12 Dimethicone, PEG-40 Hydrogenated Castor Oil, PEG-8 Dilaurate, Persea Gratissima (Avocado) Oil. Phenoxyethanol, Phospholipids, Polysorbate 20, Polysorbate 60, PPG-26-Buteth-26, Punica Granatum Seed Extract, Retinyl Palmitate, Salicylic Acid, Santalum Spicatum Seed Oil, Simmondsia Chinensis (Jojoba) Seed Oil, Sodium Benzoate, Sodium Bicarbonate, Tocopheryl Acetate, Undecylenic Acid, Urea, Water

## **FUNGUS MASTER ANTIFUNGAL TREATMENT**

miconazole nitrate lotion

Product Type HUMAN OTC DRUG Item Code (Source) NDC:72654-001

**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 mL			

Ingredient Name	Strength
CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO)	
ARGININE (UNII: 94Z LA3W45F)	
ASCORBYL PALMITATE (UNII: QN83US2B0N)	
SAFFLOWER OIL (UNII: 65UEH262IS)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
CINNAMON LEAF OIL (UNII: S92U8SQ71V)	
ORANGE OIL (UNII: AKN3KSD11B)	
COCONUT OIL (UNII: Q9L0O73W7L)	
EAST INDIAN LEMONGRASS OIL (UNII: UPOM8M3VZW)	
DIMETHYL ISOSORBIDE (UNII: SA6A6V432S)	
DODECANE (UNII: 11A386X1QH)	
EUCALYPTUS OIL (UNII: 2R040Ni662)	
CLOVE OIL (UNII: 578389D6D0)	
GLYCERIN (UNII: PDC6A3C0OX)	
MANUKA OIL (UNII: M6QU9ZUH2X)	
TEA TREE OIL (UNII: VIF565UC2G)	
PEPPERMINT OIL (UNII: AV092KU4JH)	
PANTHENOL (UNII: WV9CM0067Z)	
PEG-12 DIMETHICONE (UNII: ZEL54N6W95)	
POLYOXYL 40 HYDROGENATED CASTOR OIL (UNII: 7YC686GQ8F)	
PEG-8 DILAURATE (UNII: FC11NGP7E6)	
AVOCADO OIL (UNII: 6VNO72PFC1)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
POLYSORBATE 60 (UNII: CAL22UVI4M)	
PPG-26-BUTETH-26 (UNII: 2II1K6TZ4P)	
POMEGRANATE SEED (UNII: 7294Z34NS7)	
VITAMIN A PALMITATE (UNII: 1D1K0N0VVC)	
SALICYLIC ACID (UNII: O414PZ4LPZ)	
JOJOBA OIL (UNII: 724GKU717M)	

SODIUM BENZOATE (UNII: OJ245FE5EU)	
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	
.ALPHATOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
UNDECYLENIC ACID (UNII: K3D86KJ24N)	
UREA (UNII: 8W8T17847W)	
WATER (UNII: 059QF0KO0R)	

	Packaging				
7	# Item Code	Package Description	Marketing Start Date	Marketing End Date	
:	NDC:72654- 001-01	30 mL in 1 BOTTLE, WTH APPLICATOR; Type 0: Not a Combination Product	11/01/2019		
:	NDC:72654- 001-02	59 mL in 1 BOTTLE, WTH APPLICATOR; Type 0: Not a Combination Product	11/01/2019		

Marketing Information					
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
OTC Monograph Drug	M005	11/01/2019			

## Labeler - Ebanel Laboratories, Inc (079352161)

Revised: 12/2023 Ebanel Laboratories, Inc