# FUNGUS MASTER- miconazole nitrate lotion Clinical Resolution Laboratory, Inc.

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Active Ingredient: Miconazole Nitrate 2%

### **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 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.

## **Warnings**

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

### Uses

■ Proven clinically effective in the treatment of most athlete's foot (tinea pedis), jock itch (tinea cruris), and ringworm (tinea corporis).

### Other Information

- Shake well before use.
- Keep away from direct sunlight or heat. Store at room temperature 15°-30°C (59°-86°F).
- Keep out of reach of children.
- In case of accidental overdose or ingestion, call a doctor or poison control center immediately.
- Do not use this product if seal is broken or missing.

# **Inactive Ingredients**

Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Arginine HCl, Ascorbyl Palmitate, Butyrospermum Parkii (Shea) Butter, Caprylyl Glycol, Cetearyl Alcohol, Cinnamomum Zeylanicum Leaf Oil, Citrus Aurantium Dulcis (Orange) Peel Oil, Cocos Nucifera (Coconut) Oil, Cymbopogon Flexuosus Oil, Dimethyl Isosorbide, Disodium EDTA, Dodecane, Ethylhexylglycerin, Eucalyptus Globulus Leaf Oil, Eugenia Caryophyllus (Clove) Bud Oil, Fusanus Spicatus Wood (Sandalwood) Oil, Glycerin, Hexylene Glycol, Hydroxyethyl Acrylate/Sodium Acryloyldimethyl Taurate Copolymer, Lavandula Angustifolia (Lavender) Oil, Leptospermum Scoparium Branch/Leaf Oil, Melaleuca Alternifolia (Tea Tree) Leaf Oil, Mentha Piperita (Peppermint) Oil, Origanum Vulgare (Oregano) Leaf Oil, Panthenol, PEG-

12 Dimethicone, PEG-4 Dilaurate, PEG-40 Hydrogenated Castor Oil, Persea Gratissima (Avocado) Oil, Phenoxyethanol, Phospholipids, Polysorbate 20, Polysorbate 60, PPG-26-Buteth-26, Retinyl Palmitate, Salicylic Acid, Simmondsia Chinensis (Jojoba) Seed Oil, Sodium Benzoate, Sodium Bicarbonate, Squalane, Tocopheryl Acetate, Triethanolamine, Undecylenic Acid, Urea, Water, Xanthan Gum

Purpose..... Antifungal



### **DRUG FACTS** (Continued) DRUG FACTS (Continued) DRUG FACTS (Continued) **DRUG FACTS** (Continued) Avoid contact with the the toes; wear well-fitting, Acrylate Crosspolymer, (Peppermint) Oil, Origanum eyes. ventilated shoes, and Arginine, Ascorbyl Palmitate, Vulgare Leaf Oil, Panthenol, change shoes and socks at ■ If irritation occurs or if Carthamus Tinctorius PEG-12 Dimethicone, PEG-40 there is no improvement least once daily. For (Safflower) Seed Oil, Cetearyl Hydrogenated Castor Oil, athlete's foot and ringworm, within 4 weeks for the Alcohol, Cinnamomum PÉG-8 Dilaurate, Persea use daily for 4 weeks; for treatment of athlete's foot Zeylanicum Leaf Oil, Citrus Gratissima (Avocado) Oil, jock itch, use daily for 2 and ringworm, or 2 weeks Aurantium Dulcis (Orange) Phenoxyethanol, weeks. If condition persists for the treatment of jock Phospholipids, Polysorbate 20. Peel Oil, Cocos Nucifera longer, consult a doctor. This itch, discontinue use and (Coconut) Oil, Cymbopogon Polysorbate 60, product is not effective on consult a doctor. Flexuosus Oil, Dimethyl PPG-26-Buteth-26, Punica the scalp or nails. **Directions** Isosorbide, Dodecane, Granatum Seed Extract, Other Information Clean the affected area and Eucalyptus Globulus Leaf Oil, Retinyl Palmitate, Salicylic Keep away from direct dry thoroughly. Apply a thin Eugenia Caryophyllus (Clove) Acid, Santalum Spicatum sunlight or heat. Store at layer of the product over Flower Oil, Glycerin, Seed Oil, Simmondsia room temperature 15°-30°C (59°-86°F). Keep out of affected area twice daily Lavandula Angustifolia Chinensis (Jojoba) Seed Oil, (morning and night) or as reach of children. Do not use (Lavender) Flower Oil, Sodium Benzoate, Sodium directed by a doctor. Leptospermum Scoparium Bicarbonate, Tocopheryl this product if seal is broken Supervise children in the use Branch/Leaf Oil, Melaleuca Acetate, Undecylenic Acid, or missing. of this product. For athlete's Inactive Ingredients Acrylates/C10-30 Alkyl Alternifolia (Tea Tree) Leaf Oil, Urea, Water foot: Pay special attention to Mentha Piperita spaces between



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# **FUNGUS MASTER**

miconazole nitrate lotion

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63742-098	
Route of Administration	TOPICAL			

Active Ingredient/Active Moiety				
Ingredient Name	<b>Basis of Strength</b>	Strength		
MICONAZOLE NITRATE (UNII: VW4H1CYW1K) (MICONAZOLE - UNII:7NNO0D7S5M)	MICONAZOLE NITRATE	20 mg in 1 g		

Inactive Ingredients	
Ingredient Name	Strength
MENTHA PIPERITA (PEPPERMINT) OIL (UNII: AV092KU4JH)	
PANTHENOL (UNII: WW9CM0O67Z)	
PEG-12 DIMETHICONE (UNII: ZEL54N6W95)	
UREA (UNII: 8W8T17847W)	
PEG-40 HYDROGENATED CASTOR OIL (UNII: 7YC686GQ8F)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CITRUS AURANTIUM DULCIS (ORANGE) PEEL OIL (UNII: AKN3KSD11B)	
DIMETHYL ISOSORBIDE (UNII: SA6A6V432S)	
POLYSORBATE 60 (UNII: CAL22UVI4M)	
MELALEUCA ALTERNIFOLIA (TEA TREE) LEAF OIL (UNII: VIF565UC2G)	
TRIETHANOLAMINE (UNII: 903K93S3TK)	
ACRYLATES/C10-30 ALKYL ACRYLATE CROSSPOLYMER (60000 MPA.S) (UNII: 8Z5ZAL5H3V)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
HEXYLENE GLYCOL (UNII: KEH0A3F75J)	
LEPTOSPERMUM SCOPARIUM BRANCH/LEAF OIL (UNII: M6QU9ZUH2X)	
BUTYROSPERMUM PARKII (SHEA) BUTTER (UNII: K49155WL9Y)	
CYMBOPOGON FLEXUOSUS OIL (UNII: UPOM8M3VZW)	
HYDROXYETHYL ACRYLATE/SODIUM ACRYLOYLDIMETHYL TAURATE COPOLYMER (45000 MPA.S AT 1%) (UNII: 86FQE96TZ4)	
UNDECYLENIC ACID (UNII: K3D86KJ24N)	
CINNAMOMUM ZEYLANICUM LEAF OIL (UNII: S92U8SQ71V)	
SIMMONDSIA CHINENSIS (JOJOBA) SEED OIL (UNII: 724GKU717M)	
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	
GLYCERIN (UNII: PDC6A3C0OX)	
EUGENIA CARYOPHYLLUS (CLOVE) BUD OIL (UNII: 578389D6D0)	
COCOS NUCIFERA (COCONUT) OIL (UNII: Q9L0073W7L)	
ORIGANUM VULGARE LEAF OIL (UNII: 7D0CGR40U1)	
DISODIUM EDTA-COPPER (UNII: 6V475AX06U)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
LAVANDULA ANGUSTIFOLIA (LAVENDER) OIL (UNII: ZBP1YXW0H8)	
FUSANUS SPICATUS WOOD OIL (UNII: H9LVS6REV4)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
PPG-26-BUTETH-26 (UNII: 2II1K6TZ4P)	
PEG-4 DILAURATE (UNII: KCR71CW036)	
SALICYLIC ACID (UNII: O414PZ4LPZ)	
CETEARYL ALCOHOL (UNII: 2DMT128M1S)	
ARGININE HYDROCHLORIDE (UNII: F7LTH1E20Y)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
EUCALYPTUS OIL (UNII: 2R040NI662)	
XANTHAN GUM (UNII: TTV12P4NEE)	
PERSEA GRATISSIMA (AVOCADO) OIL (UNII: 6VNO72PFC1)	
SQUALANE (UNII: GW89575KF9)	
RETINYL PALMITATE (UNII: 1D1K0N0VVC)	
ASCORBYL PALMITATE (UNII: QN83US2B0N)	
.ALPHATOCOPHEROL ACETATE, D- (UNII: A7E6112E4N)	
DODECANE (UNII: 11A386X1QH)	

EGG PHOSPHOLIPIDS (UNII: 1Z74184RGV)
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WATER (UNII: 059QF0KO0R)

Contains

Product Characteristics			
Color	white (Yellowish offwhite)	Score	
Shape		Size	
Flavor		Imprint Code	

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:63742- 098-01	30 g in 1 BOTTLE, GLASS; Type 0: Not a Combination Product	06/06/2025		
2	NDC:63742- 098-02	59 g in 1 BOTTLE, GLASS; Type 0: Not a Combination Product	06/06/2025		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M005	06/06/2025	

# **Labeler -** Clinical Resolution Laboratory, Inc. (825047942)

# **Registrant -** Clinical Resolution Laboratory, Inc. (825047942)

Establishment				
Name	Address	ID/FEI	<b>Business Operations</b>	
Clinical Resolution Laboratory, Inc.		825047942	manufacture(63742-098)	

Revised: 6/2025 Clinical Resolution Laboratory, Inc.