MICRO-GUARD (AF)- miconazole nitrate powder Coloplast Manufacturing US, LLC

Micro-Guard®Powder Antifungal Powder With Miconazole Nitrate 2%

For Effective Treatment of Topical Fungal Infections AF

Drug Facts

Active ingredient

Miconazole Nitrate, 2%

Purpose

Antifungal

Uses Treats jock itch, ringworm, and athlete's foot ▶

Warnings

For external use only.

When using this product

- avoid contact with the eyes
- if eye contact occurs, flush with water
- do not use on children under 2 years of age unless directed by a doctor.

Stop using this product

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

Keep this and all drugs out of reach of children.

If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- clean the affected area and dry thoroughly
- apply over the 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.

Inactive ingredients corn starch USP, sodium bicarbonate, tri-calcium phosphate

Manufactured for Coloplast A/S DK-3050 Humlebaek, Denmark Distributed by: Coloplast Corp. Minneapolis, MN 55411 U.S.A. 1-800-533-0464 www.us.coloplast.com **Product #1337**

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PRINCIPAL DISPLAY PANEL - 3 OZ. (85 g)

NDC 11701-038-16

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For Effective Treatment of Topical Fungal Infections

ΑF

Coloplast

3 OZ. (85 g)

L8-640



MICRO-GUARD (AF) miconazole nitrate powder **Product Information Product Type HUMAN OTC DRUG Item Code (Source)** NDC:11701-038 **Route of Administration TOPICAL Active Ingredient/Active Moiety**

3-11701-03816-3

Ingredient Name	Basis of Strength	Strength
MICONAZOLE NITRATE (UNII: VW4H1CYW1K) (MICONAZOLE - UNII:7NNO0D7S5M)	MICONAZOLE NITRATE	20 mg in 1 g

Inactive Ingredients	
Ingredient Name	Strength
STARCH, CORN (UNII: O8232NY3SJ)	
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	
TRIBASIC CALCIUM PHOSPHATE (UNII: 91D9GV0Z28)	

Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:11701-038-	85 g in 1 BOTTLE; Type 0: Not a Combination Product	06/15/2009	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph drug	M005	06/15/2009	

Labeler - Coloplast Manufacturing US, LLC (110326675)

Registrant - Coloplast Corp (847436391)

Establishment				
Name	Address	ID/FEI	Business Operations	
Coloplast Manufacturing US, LLC		110326675	MANUFACTURE(11701-038)	

Revised: 12/2023 Coloplast Manufacturing US, LLC