MICRO-GUARD (MICONAZOLE NITRATE) POWDER [COLOPLAST MANUFACTURING US, LLC]

Description *(if available)*:

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

PRINCIPAL DISPLAY PANEL - 3 OZ. (85 g)

NDC 11701-038-16

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

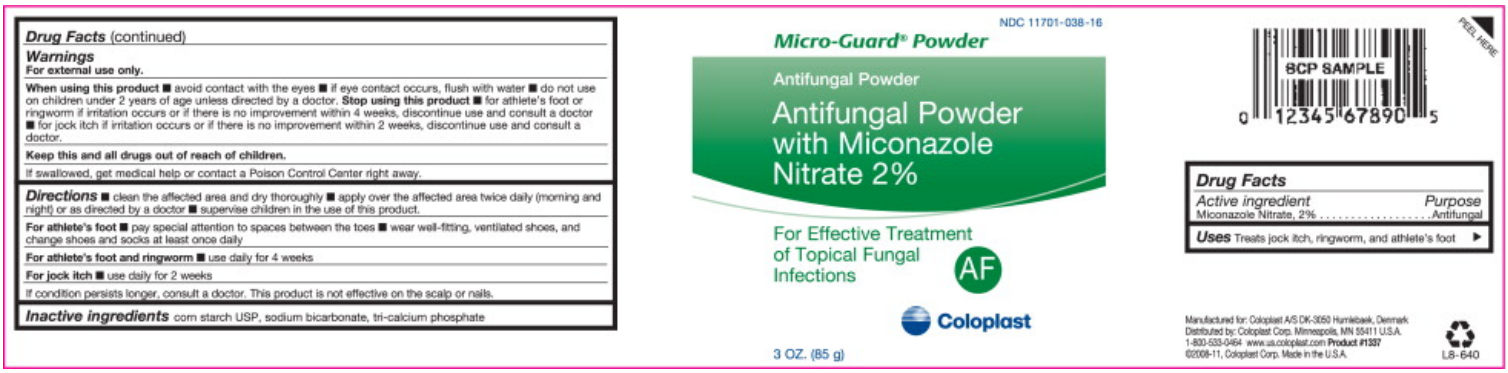
For Effective Treatment of Topical Fungal Infections

AF

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	DEA Schedule	

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MICONAZOLE NITRATE (MICONAZOLE)	MICONAZOLE NITRATE	20 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
STARCH, CORN	
SODIUM BICARBONATE	
TRIBASIC CALCIUM PHOSPHATE	

Product Characteristics

Color		Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Multilevel Packaging
1	NDC:11701-038-16	85 g in 1 BOTTLE	None

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date

OTC monograph final	part333C	06/15/2009

Labeler - Coloplast Manufacturing US, LLC (110326675)

Registrant - Coloplast Corp (847436391)

Establishment

Name	Address	ID/FEI	Operations
Coloplast Manufacturing US, LLC		110326675	MANUFACTURE

Revised: 06/2011 Coloplast Manufacturing US, LLC