

## **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](http://www.us.coloplast.com) Product #1337

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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

**Drug Facts** (continued)

**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** com starch USP, sodium bicarbonate, tri-calcium phosphate

NDC 11701-038-16

**Micro-Guard® Powder**  
Antifungal Powder  
**Antifungal Powder with Miconazole Nitrate 2%**

For Effective Treatment of Topical Fungal Infections

AF

Coloplast

3 OZ. (85 g)

8CP SAMPLE  
0 12345 67890 5

**Drug Facts**

Active ingredient	Purpose
Miconazole Nitrate, 2%	Antifungal

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

Manufactured for: Coloplast A/S DK-3050 Humlebaek, Denmark  
Distributed by: Coloplast Corp. Minneapolis, MN 55411 U.S.A.  
1-800-533-0484 www.us.coloplast.com Product #1337  
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LS-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
<b>MICONAZOLE NITRATE (MICONAZOLE)</b>		MICONAZOLE NITRATE	20 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
<b>STARCH, CORN</b>	
<b>SODIUM BICARBONATE</b>	
<b>TRIBASIC CALCIUM PHOSPHATE</b>	

Product Characteristics

Color	Score
Shape	Size
Flavor	Imprint Code
Contains	

Packaging

# Item Code	Package Description	Multilevel Packaging
<b>1</b> 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
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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