

LOTRIMIN ANTIFUNGAL- miconazole nitrate powder

Bayer HealthCare LLC

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Lotrimin®

Antifungal

Drug Facts

Active ingredient

Miconazole nitrate 2%

Purpose

Antifungal

Uses

- Cures most athlete's foot (tinea pedis), jock itch (tinea cruris) and ringworm (tinea corporis)
- relieves itching, cracking, burning and scaling

Warnings

For external use only

Avoid contact with the eyes

Stop use and ask a doctor if

- irritation occurs
- if there is no improvement within 4 weeks (for athlete's foot and ringworm) or 2 weeks (for jock itch)

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- wash affected area and dry thoroughly
- sprinkle a thin layer over affected area twice daily (morning and night)
- 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, ask a doctor
- this product is not effective on the scalp or nails

Other information

store between 20° to 25°C (68° to 77°F)

Inactive ingredients

benzethonium chloride, corn starch, kaolin, sodium bicarbonate, starch/acrylates/acrylamide copolymer, zinc oxide

PRINCIPAL DISPLAY PANEL - 90g Can Label

NDC 11523-0919-1

LOTRIMIN[®] AF

ANTIFUNGAL

miconazole nitrate

Cures Most

Athlete's Foot

POWDER

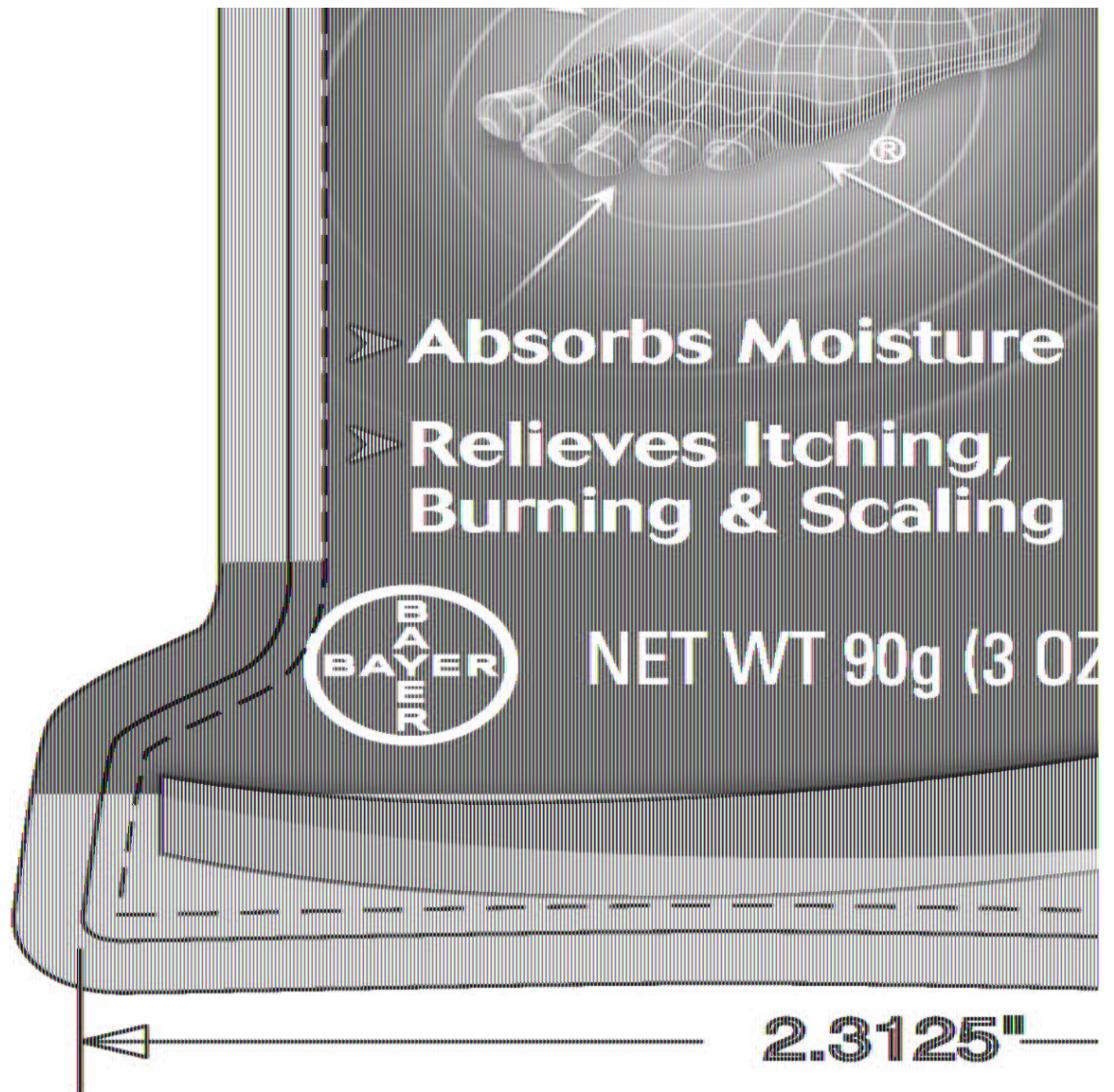
- Absorbs Moisture
- Relieves Itching,

Burning & Scaling

NET WT 90g (3 OZ)

37871-00





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- > Relieves Itching, Burning & Scaling



NET WT 90g (3 OZ)

2.3125"

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Active Ingredient

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Purpose

Antifungal

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Warnings

For external use only

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

When using this product avoid contact with the eyes

Stop use and ask a doctor if

= irritation occurs = there is no improvement within 4 weeks (for athlete's foot and ringworm) or 2 weeks (for jock itch)

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

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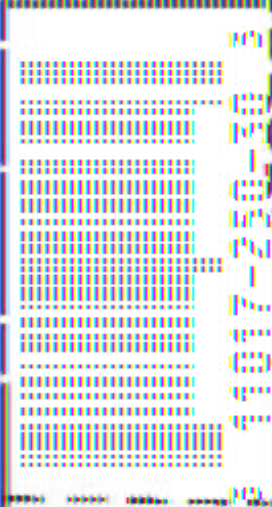
Questions? 1-866-360-3228

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Made by Bayer HealthCare LLC

Whisper, NJ 07984 Product of South

Bayer



LOTRIMIN ANTIFUNGAL

miconazole nitrate powder

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:11523-0919
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 g

Inactive Ingredients

Ingredient Name	Strength
BENZETHONIUM CHLORIDE (UNII: PH41D05744)	
STARCH, CORN (UNII: O8232NY3SJ)	
KAOLIN (UNII: 24H4NWX5CO)	
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	
ZINC OXIDE (UNII: SOI2LOH54Z)	

Product Characteristics

Color	white (White to off-white)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:11523-0919-1	90 g in 1 CAN; Type 0: Not a Combination Product	09/01/1993	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333C	09/01/1993	

Labeler - Bayer HealthCare LLC (968091715)

Revised: 6/2016

Bayer HealthCare LLC