LOTRIMIN ANTIFUNGAL- miconazole nitrate aerosol, 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

- proven clinically effective in the treatment of most athlete's foot (tinea pedis), jock itch (tinea cruris) and ringworm (tinea corporis)
- for effective relief of itching, cracking, burning, scaling and discomfort

Warnings

For external use only

Flammable: Do not use while smoking or near heat or flame

Do not use on children under 2 years of age except under the advice and supervision of a doctor.

When using this product

- avoid contact with the eyes
- use only as directed. Intentional misuse by deliberately concentrating and inhaling contents can be harmful or fatal
- contents under pressure. Do not puncture or incinerate. Do not store at temperature above 120°F.

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.

Directions

- wash affected area and dry thoroughly
- shake can well and spray 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
- in case of clogging, clean nozzle with a pin

Other information

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

Inactive ingredients

isobutane, SD alcohol 40-B (8% v/v), stearalkonium hectorite, talc

Questions?

1-866-360-3266

Distribution

Distributed by: Bayer HealthCare LLC, Whippany NJ

PRINCIPAL DISPLAY PANEL - 133 g Can Label

Powder Spray

goes on dry

NDC 11523-0544-2

LOTRIMIN® AF

ANTIFUNGAL

miconazole nitrate

Clinically Proven To Cure

Most Athlete's Foot

· Relieves Itching,

Burning, Cracking

& Scaling

NET WT 133g (4.6 OZ)



LOTRIMIN ANTIFUNGAL

miconazole nitrate aerosol, powder

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:11523-0544
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		
ISOBUTANE (UNII: BXR49TP611)			
TALC (UNII: 7SEV7J4R1U)			

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

ı	P	Packaging			
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	1	NDC:11523- 0544-2	133 g in 1 CAN; Type 0: Not a Combination Product	09/01/1993	

Marketing In	arketing 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. (112117283)

Revised: 9/2023 Bayer Healthcare LLC.