LOTRIMIN AF ANTIFUNGAL- miconazole nitrate spray 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 ® AF

Antifungal Liquid

Drug Facts

Active ingredient

(To Deliver) 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 unless directed by a doctor

When using this product

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

Other information

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

Inactive ingredients

dimethyl ether, polyoxyl 15 hydroxystearate, sd alcohol 40-B (16.5% v/v)

Questions?

1-866-360-3266

Distribution

Distributed by Bayer HealthCare LLC Whippany, NJ 07981 USA

PRINCIPAL DISPLAY PANEL - 133 g Can Label

Liquid Spray

cools the burn

NDC 11523-4327-01

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 AF ANTIFUNGAL

miconazole nitrate sprav

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:11523-4327
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		
DIMETHYL ETHER (UNII: AM13FS69BX)			

l	Packaging				
	# Item Code	Package Description	Marketing Start Date	Marketing End Date	
	1 NDC:11523-4327-1	133 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. (112117283)

Revised: 9/2023 Bayer Healthcare LLC.