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 jock itch (tinea cruris)
- for effective relief of itching, burning, scaling and discomfort, and chafing associated with jock itch

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 2 weeks

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
- 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

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 07981 USA

PRINCIPAL DISPLAY PANEL - 133 g Can Label

Powder Spray

goes on dry

NDC 11523-4140-2

LOTRIMIN® AF

ANTIFUNGAL

miconazole nitrate

Clinically Proven To Cure

Most Jock Itch

Relieves Itching,

Burning, Scaling



LOTRIMIN ANTIFUNGAL

miconazole nitrate aerosol, powder

miconazole nitrate aerosol, powder						
Product Information						
Product Type	HUMAN OTC DRUG	Item Code (Sou	rce)	NDC:1152	23-4140	
Route of Administration	TOPICAL					
Active Ingredient/Active Moiety						
Ingredient Name			Basis of S	trength	Streng	jth
MICONAZOLE NITRATE (UNII: VW4H1CYW1K) (MICONAZOLE - UNII:7NNO0D7S5M)			MICONAZOLE	NITRATE	20 mg ii	1 1 g

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Inactive Ingredients			
Ingredient Name	Strength		
TALC (UNII: 7SEV7J4R1U)			
ISOBUTANE (UNII: BXR49TP611)			

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- 4140-2	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.