TOLNAFTATE- antifungal powder spray aerosol, spray Topco Associates 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.

TopCare Antifungal Powder Spray

Active ingredient

Tolnaftate 1%

Purpose

Antifungal

Uses

- cures most athlete's foot (tinea pedis), ringworm (tinea corporis) and jock itch (tinea cruris)
- can prevent recurrence of most athlete's foot
- relieves symptoms of athlete's foot, including itching, burning, cracking and chafing associated with jock itch

Warnings

For external use only.

Flammable:

Do not use while smoking or near heat or flame. Do not puncture or incinerate. Contents under pressure. Do not store at temperature above 120°F. Intentional misuse by deliberately concentrating and inhaling contents cans be harmful or fatal.

When using this product

- do not get into eves or mouth
- use only as directed

Stop use and ask a doctor if

- irritation occurs
- no improvement within 4 weeks for athlete's foot, ringworm and 2 weeks for jock itch

Do not use

on children under 2 years of age unless directed by a doctor.

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) 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
- use daily for 4 weeks for athletes foot, ringworm and for jock itch use daily for 2 weeks
- if conditions persist, consult a doctor
- to prevent athlete's foot, apply daily once or twice daily (morning and/or night)
- this product is not effective on the scalps or nails
- in case of clogging, clear nozzle under running water

Other information

store between 20° and 30°C (68°F and 86°)

Inactive ingredient

BHT, isobutane (propellent), PPG-12-buteth-16, SD alcohol 40-B (14%w/w), talc

Questions?

Call 1-888-423-0139

Principal Display Panel

TopCare

MEDICATED

Antifungal Powder Spray

TOLNAFTATE 1%

- Cures most athlete's foot and most recurrences
- Soothes itching & burning

NET WT 4.6 OZ (130g)



MEDICATED

Antifungal Powder

TOLNAFTATE 1%

- Cures most athlete's foot and most recurrences
- Soothes itching & burning



COMPARE TO TINACTIN® active ingredient*

NET WT 4.6 OZ (130g)

Drug Facts

Active ingredient Tolnaftate 1%

Purpose Antifungal

Uses ■ cures most athlete's foot (tinea pedis), ringworm (tinea corporis) and jock itch (tinea cruris) ■ can prevent recurrence of most athlete's foot ■ relieves symptoms of athlete's foot, including itching, burning, cracking and chafing associated with jock itch

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When using this product a avoid contact with the eyes or mouth

■ use only as directed

Stop use and ask a doctor if ■ no improvement within 4 weeks for athlete's foot, ringworm and 2 weeks for jock itch ■ irritation occurs

Do not use on children under 2 years of age unless directed by a doctor. Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

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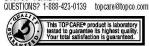
running water Other information store between 20° and 30°C (68° and 86°F)

Inactive ingredients BHT,

isobutane (propellant), PPG-12-buteth-16, SD Alcohol 40-B (14% w/w), talc

Questions? Call 1-888-423-0139

DISTRIBUTED BY TOPCO ASSOCIATES LLC ELK GROVE VILLAGE, IL 60007 ©TOPCO PBA1214





50-060TC

TOLNAFTATE

antifungal powder spray aerosol, spray

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:36800-012

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name Basis of Strength Strength TOLNAFTATE (UNII: 06KB629TKV) (TOLNAFTATE - UNII:06KB629TKV) TOLNAFTATE 1.3 g in 130 g

Inactive Ingredients

Ingredient Name	Strength			
BUTYLATED HYDRO XYTO LUENE (UNII: 1P9 D0 Z171K)				
ISOBUTANE (UNII: BXR49TP611)				
PPG-12-BUTETH-16 (UNII: 58CG7042J1)				
ALCOHOL (UNII: 3K9958V90M)				
TALC (UNII: 7SEV7J4R1U)				

Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1 1	NDC:36800-012-46	130 g in 1 CAN; Type 0: Not a Combination Product	0 1/0 3/20 12	01/04/2021	
Marketing Information					
M	arketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
ОТ	C monograph final	part333C	0 1/0 3/20 12	01/04/2021	

Labeler - Topco Associates LLC (006935977)

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