KERASAL ATHLETES FOOT POWDER- tolnaftate spray Advantice Health, 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.

Kerasal® Athlete's Foot Powder Spray

Drug Facts

Active ingredient

(To Deliver) Tolnaftate 1%

Purpose

Antifungal

Uses

- Proven clinically effective in the treatment of most athlete's foot (tinea pedis)
- Helps prevent most athlete's foot with daily use
- For effective relief of itching, cracking, burning, scaling and discomfort

Warnings

For external use only

Extremely 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 doctor if

- Irritation occurs
- There is no improvement within 4 weeks.

Keep out of reach of children. If swallowed, get medical help or contact a poison control center right away.

Directions

- Wash the 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
- 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; if condition persists longer, ask a doctor
- To prevent athlete's foot, apply once or twice daily (morning and/or night, or as directed by a doctor)
- This product is not effective on the scalp or nails.

Other information

Store between 20-25°C (68-77°F)

Inactive ingredients

alcohol, aloe vera leaf, alpha-tocopherol acetate, butylated hydroxytoluene, ceramide NG, dimethicone, eucalyptus oil, isobutane, isododecane, methylal, peppermint oil, tapioca starch, tea tree oil

Questions?

1-877-674-3475 www.Kerasal.com

PRINCIPAL DISPLAY PANEL - 56 g Can Label

Tolnaftate Antifungal Kerasal®

NFW

For Athlete's Foot

Invisible Powder Spray

5 IN 1™

CURES

Most Athlete's Foot

PREVENTS

Recurrence

RELIEVES

Itching, Burning And Scaling

NOURISHES

Improves Skin Appearance

DEODORIZES

With Essential Oils

Enriched with Natural Tea Tree Oil.



KERASAL ATHLETES FOOT POWDER

REMASAL ATTILLIES FOOT FOWDER						
tolnaftate spray						
Product Information						
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:16	8864-110	
Route of Administration	TOPICAL					
A . 1 . 1	N. 4 . 4 . 1					
Active Ingredient/Active Moiety						
Ingred	lient Name		Basis of Stre	ngth	Strength	
TOLNAFTATE (UNII: 06KB629TKV)	(TOLNAFTATE - UNII:06KB62	29TKV)	TOLNAFTATE		1 g in 100 g	
Inactive Ingredients						

Strength

Ingredient Name

ALCOHOL (UNII: 3K9958V90M)	
.ALPHATOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
CERAMIDE NG (UNII: C04977SRJ5)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
EUCALYPTUS OIL (UNII: 2R04ONI662)	
ISOBUTANE (UNII: BXR49TP611)	
ISODODECANE (UNII: A8289P68Y2)	
PEPPERMINT OIL (UNII: AV092KU4JH)	
STARCH, TAPIOCA (UNII: 24SC3U704I)	
TEA TREE OIL (UNII: VIF565UC2G)	

Ш	Packaging						
	# Item Code	Package Description	Marketing Start Date	Marketing End Date			
	NDC:16864-110- 01	57 g in 1 CAN; Type 0: Not a Combination Product	02/28/2022				

Marketing Information						
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date			
OTC MONOGRAPH FINAL	part333C	02/28/2022				

Labeler - Advantice Health, LLC (192527062)

Revised: 5/2022 Advantice Health, LLC