WINCO ANTIFUNGAL- tolnaftate cream Winco Foods, 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.

Winco Antifungal Tolnaftate 1% Cream 1 oz 24193 ZDP (2021)

Active ingredient Purpose

Tolnaftate 1%......Antifungal

Uses

- proven clinically effective in the treatment of most athlete's foot (tinea pedis) and ringworm (tinea corporis)
- helps prevent most athlete's foot with daily use
- for effective relief of itching, burning and cracking

Warnings

For external use only

Do not use on 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.

Stop use and ask a doctor if

- irritation occurs
- there is no improvement within 4 weeks

If pregnant or breast-feeding, ask a health professional before use.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center (1-800-222-1222) right away.

Directions

- wash affected area and dry thoroughly
- apply a thin layer of the product 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
- for athlete's foot and ringworm, use daily for 4 weeks. If condition persists longer, consult a doctor
- to prevent athlete's foot, apply once or twice daily (morning and/or night)
- this product is not effective on the scalp or nails

Other information

• store at room temperature 20-25°C (68-77°F)

Inactive ingredient cetostearyl alcohol, ethylparaben, glycerin, glyceryl monostearate,

petrolatum, propylene glycol, purified water, sodium sulfite, steareth-20, stearic acid

Distributed by:

Winco Foods, LLC Boise, ID 83704 Made in China



TAMPER EVIDENT: DO NOT USE IF CARTON IS OPEN OR FOIL UNDER CAP IS BROKEN OR MISSING.

Drug Facts (continued)

PurposeAntifungal

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Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:67091-190

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TOLNAFTATE (UNII: 06KB629TKV) (TOLNAFTATE - UNII:06KB629TKV)	TOLNAFTATE	10 ma in 1 a

Inactive Ingredients				
Ingredient Name	Strength			
GLYCERIN (UNII: PDC6A3C0OX)				
PETROLATUM (UNII: 4T6H12BN9U)				
SODIUM SULFITE (UNII: VTK01UQK3G)				
STEARETH-20 (UNII: L0Q8IK9E08)				
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)				
ETHYLPARABEN (UNII: 14255EXE39)				
GLYCERYL MONOSTEARATE (UNII: 2300U9XXE4)				
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)				
WATER (UNII: 059QF0KO0R)				
STEARIC ACID (UNII: 4ELV7Z65AP)				

F	Packaging					
#	tem Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:67091-190- 28	1 in 1 CARTON	01/12/2021			
1		28 g in 1 TUBE; Type 0: Not a Combination Product				

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	part333C	01/12/2021		

Labeler - Winco Foods, LLC (056098817)

Revised: 1/2022 Winco Foods, LLC