WINCO FOODS TOLNAFTATE- 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, 2018)

Active ingredient (in each gram) Purpose

Tolnaftate 1%------ Antifungal

Uses

- Proven clinically effective in the treatment of athlete's foot (tinea pedis) and rignworm (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 children under 2 years of age unless directed by 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

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 thoroguhly
- apply 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
- 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)
- this product is not effective on the scalp or nails

Other information

- store between 20° to 25C° (68° to 77F°)
- Lot No & Exp. Date: see box or see crimp of tube

Inactive ingredients

buylated hydroxytoluene, ceteth-20, cetyl alcohol, methylparaben, mineral oil, propylene

glycol, propylparaben, sorbitan monostearate, stearyl alcohol, water DISTRIBUTED BY:
WINCO FOODS, LLC,
BOISE, ID 83704
MADE IN KOREA



tolnaftate cream

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:67091-276

Route of Administration TOPICAL

Active Ingredient/Active Moiety

	Ingredient Name	Basis of Strength	Strength
l	TOLNAFTATE (UNII: 06KB629TKV) (TOLNAFTATE - UNII:06KB629TKV)	TOLNAFTATE	10 mg in 1 g

Inactive Ingredients				
Ingredient Name	Strength			
CETETH-20 (UNII: 1835H2IHHX)				
CETYL ALCOHOL (UNII: 936JST6JCN)				
METHYLPARABEN (UNII: A2I8C7HI9T)				
MINERAL OIL (UNII: T5L8T28FGP)				
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)				
PROPYLPARABEN (UNII: Z8IX2SC1OH)				
SORBITAN MONOSTEARATE (UNII: NVZ 4I0H58X)				
STEARYL ALCOHOL (UNII: 2KR89I4H1Y)				
WATER (UNII: 059QF0KO0R)				

F	Packaging					
#	tem Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:67091-276- 28	1 in 1 BOX	05/11/2017			
1		28 g in 1 TUBE; Type 1: Convenience Kit of Co-Package				

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333C	02/06/2015	

Labeler - Winco Foods, LLC (056098817)

Revised: 8/2023 Winco Foods, LLC