DR. SCHOLLS INSTANT COOL ATHLETES FOOT WIPES- tolnaftate swab Cosco International, Inc.

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.

Active Ingredient

Tolnaftate 1%......Purpose: Antifungal

Purpose

Antifungal foot wipes

Uses

- cures most athlete's foot (tinea pedis) and ringworm (tinea corpois)
- prevents most athlete's foot (tinea pedis) and ringworm (tinea corpois) with daily use
- for effective relief of itching, burning, cracking, scaling, and discomfort which accompany these conditions

Warnings

For External use only

Do not use on children under 2 years of age unless otherwise 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 (for athlete's foot and ringworm)

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
- use the pad to cleanse and cover the affected area with a thin layer twice daily (morning and night)
- pay special attention to spaces between toes; wear well-fitting, ventilated shoes and change shoes and socks at least once daily
- supervise children in the use of this product
- for treatment of athlete's foot and ringworm, use daily for 4 weeks.
- to prevent athlete's foot, apply once or twice daily (morning and/or night)

Other Information

- KEEP TIGHTLY CLOSED
- do not flush pads in toilet
- store between 20° ro 25°C (68° to 77°F)

Inactive ingredients

Butylated Hydroxytoluene, Caprylyl Glycol, Eucalyptus Oil, Menthol, Menthoxypropanediol, Peppermint Oil, Phenoxyethanol, Polysorbate 20, Polysorbate 80, Proylene Glycol, Sodium Hydroxide, Water

Questions? 1-866-360-3226





DR. SCHOLLS INSTANT COOL ATHLETES FOOT WIPES

tolnaftate swab

Product information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:52261-8100	

Route of Administration TOPICAL

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
TOLNAFTATE (LINII: 06KB620TK)/) (TOLNAFTATE - LINII: 06KB620TK)/)	TOLNAFTATE	10 a in 1000 a	

Inactive Ingredients		
Ingredient Name	Strength	
water (UNII: 059QF0KO0R)		
SODIUM HYDROXIDE (UNII: 55X04QC32I)		

POLYSORBATE 80 (UNII: 60ZP39ZG8H)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
EUCALYPTUS OIL (UNII: 2R04ONI662)	
3-((L-MENTHYL)OXY)PROPANE-1,2-DIOL (UNII: KD6TZ2QICH)	
menthol (UNII: L7T10EIP3A)	
PEPPERMINT OIL (UNII: AV092KU4JH)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:52261- 8100-1	60 in 1 CANISTER	02/01/2022	
1		2.5 g in 1 APPLICATOR; 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	01/27/2022	

Labeler - Cosco International, Inc. (016433141)

Establishment					
Name	Address	ID/FEI	Business Operations		
Cosco International, Inc.		016433141	manufacture(52261-8100)		

Revised: 2/2022 Cosco International, Inc.