

SKINHEAL ANTIFUNGAL- tolnaftate cream
Zhejiang Dingtai Pharmaceutical Co., Ltd

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.

Drug Facts

Active ingredient

Tolnaftate 1.0%

Purpose

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 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

Adults and children 2 years of age or older:

wash the affected area and dry thoroughly

apply a thin layer of the product over the 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

change shoes and socks at least once daily

use daily for 4 weeks for the treatment of athlete's foot and ringworm

if condition persists longer, consult a doctor

use daily for the prevention of athlete's foot
 this product is not effective on the scalp or nails
 Children under 2 years: do not use unless directed by a doctor

Other information

keep container tightly closed
 store between 15 and 30 C (59 to 86 F)

Inactive ingredients cetostearyl alcohol, glycerin, glyceryl monostearate, petrolatum, propylene glycol, sodium sulfite, steareth- 20, stearic acid, and water

Questions or comments? (888) 221-3496 M-F 9am-5pm
 you may also report serious side effects to this phone number

SKINHEAL ANTIFUNGAL CREAM

Tolnaftate 1%
 Net Wt. 10 g (1/3 oz)
 NDC 69070-305-01





SKINHEAL ANTIFUNGAL

tolnaftate cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69070-305
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TOLNAFTATE (UNII: 06KB629TKV) (TOLNAFTATE - UNII:06KB629TKV)	TOLNAFTATE	1 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
GLYCERIN (UNII: PDC6A3C0OX)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
PETROLATUM (UNII: 4T6H12BN9U)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SODIUM SULFITE (UNII: VTK01UQK3G)	
STEARETH-20 (UNII: L0Q8IK9E08)	

STEARIC ACID (UNII: 4ELV7Z65AP)

WATER (UNII: 059QF0KO0R)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69070-305-01	1 in 1 BOX	12/10/2018	
1		10 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	12/10/2018	

Labeler - Zhejiang Dingtai Pharmaceutical Co., Ltd (420598724)

Establishment

Name	Address	ID/FEI	Business Operations
Zhejiang Dingtai Pharmaceutical Co., Ltd		420598724	manufacture(69070-305)

Revised: 5/2019

Zhejiang Dingtai Pharmaceutical Co., Ltd