TINACTIN- tolnaftate cream
Bayer HealthCare 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.

Tinactin ®

Drug Facts

Active ingredient

Tolnaftate 1%

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 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

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
- 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 25°C (68° to 77°F)

Inactive ingredients

ceteth-20, cetostearyl alcohol, chlorocresol, mineral oil, propylene glycol, purified water, sodium phosphate monobasic, white petrolatum

Questions?

1-866-360-3266

Distributed by

Bayer HealthCare LLC, Whippany, NJ, USA, 07981

PRINCIPAL DISPLAY PANEL - 15 g Tube Carton

TOUCH ACTIN'

Tinactin **®**

tolnaftate ***ANTIFUNGAL***

CURES AND PREVENTS

MOST ATHLETE'S FOOT

Relieves:

- ***itching***
- ***burning***
-

CREAM

NET WT 15G (1/2 OZ)

TINACTIN

tolnaftate cream

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:11523-1190
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
TOLNAFTATE (UNII: 06KB629TKV) (TOLNAFTATE - UNII:06KB629TKV)	TOLNAFTATE	10 mg in 1 g

Inactive Ingredients	
Ingredient Name	**Strength**
CETETH-20 (UNII: I835H2IHHX)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
CHLOROCRESOL (UNII: 36W53O7109)	
MINERAL OIL (UNII: T5L8T28FGP)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SODIUM PHOSPHATE, MONOBASIC (UNII: 3980JIH2SW)	
PETROLATUM (UNII: 4T6H12BN9U)	

Product Characteristics			
Color	white (White to Off-white)	**Score**	
Shape		**Size**	
Flavor		**Imprint Code**	
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:11523-1190-1	1 in 1 CARTON	12/12/2002	
1		15 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:11523-1190-2	1 in 1 CARTON	12/12/2002	
2		30 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	09/23/1993	

Labeler - Bayer HealthCare LLC. (112117283)

Revised: 9/2023 Bayer HealthCare LLC.