TOLNAFTATE- tolnaftate cream
NuCare Pharmaceuticals,Inc.

Drug Facts

Active ingredient

Tolnaftate USP 1%

Purpose

Antifungal

Uses

- for effective treatment of most athlete's foot (tinea pedis), jock itch (tinea cruris) and ringworm (tinea corporis)
- for effective relief of itchy, scaly skin between the toes
- clears up most athlete's foot infection and with daily use helps keep it from coming back

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 eyes

Stop use and ask a doctor if

- irritation occurs or if there is no improvement within 4 weeks (for athlete's foot and ringworm)
- irritation occurs or if there is no improvement within 2 weeks (for jock itch)

Keep this and all drugs out of the reach of children.

In case of accidental ingestion, seek professional assistance or contact a Poison Control Center immediately.

Directions

- clean 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

- use daily for 4 weeks. If condition persists longer, consult a doctor
- pay special attention to the spaces between the toes
- wear well fitting ventilated shoes
- change shoes and socks at least once daily

For ringworm, use daily for 4 weeks. If condition persists longer, consult a doctor.

For jock itch, use daily for 2 weeks. If condition persists longer, consult a doctor.

This product is not effective on the scalp or nails.

Other information

- Store at controlled room temperature 15°-30°C (59°-86°F)
- Lot No. and Exp date: see crimp on tube or see box

Inactive ingredients

Ceteth-20, Cetostearyl Alcohol, Chlorocresol, Mineral Oil, Propylene Glycol, Purified Water, Sodium Phosphate Monobasic, White Petrolatum

Questions?

Adverse Drug Event call (800)616-2471

Dist. By MAJOR PHARMACEUTICALS, 31778 Enterprise Drive, Livonia, MI 48150 USA

Re-Oder No. 100497 M-88 Rev. 9/09 Manufactured in USA

Principal Display Panel –

TOLNAFTATE
tolnaftate cream

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:68071-4245(NDC:0904-0722)
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
WATER (UNII: 059QF0KO0R)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
CETETH-20 (UNII: I835H2IHHX)	
CHLOROCRESOL (UNII: 36W53O7109)	
MINERAL OIL (UNII: T5L8T28FGP)	
PETROLATUM (UNII: 4T6H12BN9U)	
SODIUM PHOSPHATE, MONOBASIC, ANHYDROUS (UNII: KH7I04HPUU)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68071-4245-5	14.18 g in 1 TUBE; Type 0: Not a Combination Product	01/22/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M014	02/11/2010	

Labeler - NuCare Pharmaceuticals,Inc. (010632300)

Establishment

Name	Address	ID/FEI	Business Operations
NuCare Pharmaceuticals,Inc.		010632300	relabel(68071-4245)

Revised: 6/2024 NuCare Pharmaceuticals,Inc.