TOLNAFTATE- tolnaftate cream
NuCare Pharmaceuticals,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.

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

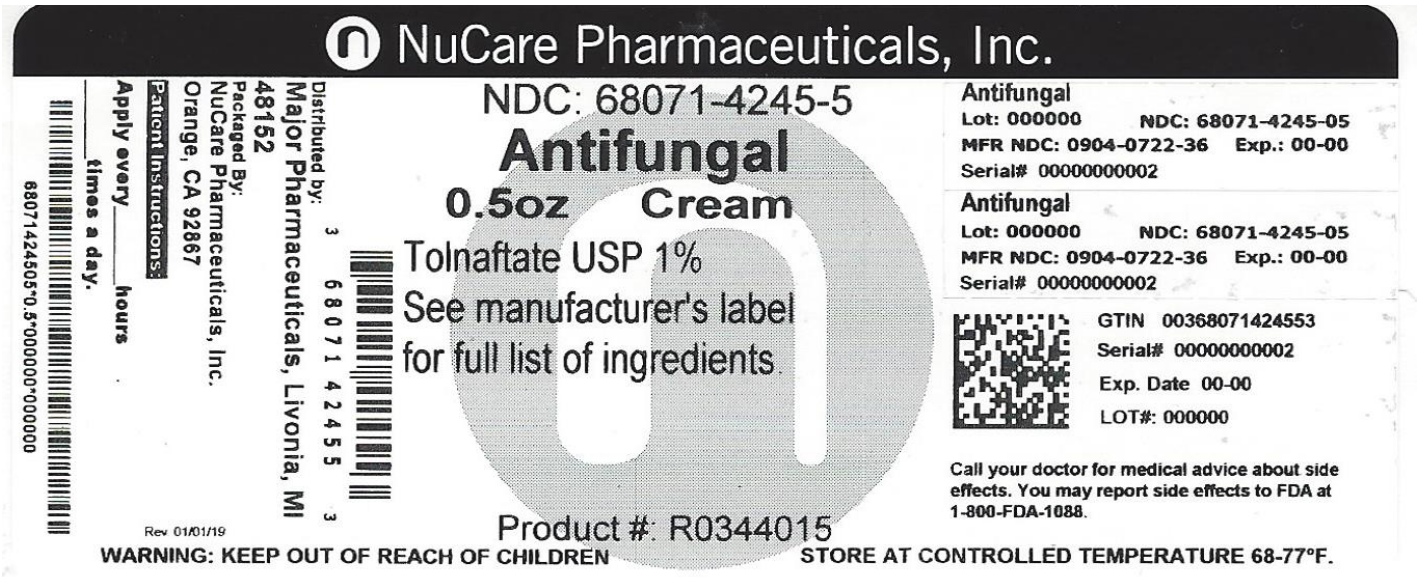
Questions?

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 final	part333C	02/11/2010	

Labeler - NuCare Pharmaceuticals,Inc. (010632300)

Establishment

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