TOLNAFTATE D- tolnaftate cream
NexMed (USA), 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

Purpose

Antifungal

Uses

- Proven clinically effective in the treatment of athlete's foot (tinea pedis), jock itch (tinea cruris), ringworm (tinea corporis)
- Proven effective in the prevention of athlete's foot
- Effectively soothes and relieves itching associated with jock itch, scaly skin between the toes and burning feet

Warnings

For external use only

When using this product

avoid contact with the eyes

Stop use and ask a doctor if

- Irritation occurs
- There is no improvement within 2 weeks (for jock itch) and 4 weeks for (athlete's foot and ringworm)

Do not use

on children under 2 years of age except under the advice and supervision of a doctor

Keep out of reach of children

If swallowed, get medical help or contact a Poison Control Center right away

Directions

- Clean the affected area and dry thoroughly
- Apply a thin layer over affected area twice a daily (morning and night) or as directed by a doctor
- Supervise children in the use of this product
- For athlete's foot, pay attention to spaces between the toes, wear well-fitting, ventilated shoes and change shoes and socks at least once daily

- For athlete’s foot and ringworm use daily for 4 weeks, 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 between 20° and 25°C (68° to 77°F)
- Lot No. and Exp. Date: see box or see crimp of tube
- Keep box for complete instructions and labeling

Inactive Ingredients

cetyl alcohol, dodecyl-2-N N-dimethylaminopropionate hydrochloride, methylparaben, mineral oil, ceteth-10, propylene glycol, propylparaben, purified water, sorbitan monostearate, stearyl alcohol

Questions?

Call 858-222-8041, Mon-Fri, 8:30 AM - 5:30PM (PST)

TOLNAFTATE D

tolnaftate cream

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:40002-002
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
Cetyl Alcohol (UNII: 936JST6JCN)	
Dodecyl-2-N,N-Dimethylaminopropionate Hydrochloride (UNII: 18F5YMF989)	
Methylparaben (UNII: A2I8C7HI9T)	
Mineral Oil (UNII: T5L8T28FGP)	
Ceteth-10 (UNII: LF9X1PN3XJ)	
Propylene Glycol (UNII: 6DC9Q167V3)	
Propylparaben (UNII: Z8IX2SC1OH)	
Water (UNII: 059QF0KO0R)	
Sorbitan Monostearate (UNII: NVZ4I0H58X)	
Stearyl Alcohol (UNII: 2KR89I4H1Y)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:40002-002-01	1 in 1 CARTON		
1	NDC:40002-002-02	28 g in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333C	08/15/2011	

Labeler - NexMed (USA), Inc. (031710528)

Registrant - NexMed (USA), Inc. (031710528)

Revised: 8/2011 NexMed (USA), Inc.