DG ATHLETES FOOT - tolnaftate cream
TAI GUK PHARM. 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 Purpose

Tolnaftate 1% .....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 4 weeks

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

- Wash affected area and dry thoroughly
- Apply a thin layer over 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 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

Lot No. and Exp. Date: see box or see crimp of the tube. Store between 20^{o} to 25^{o}C (68^{o} to 77^{o}F)

Inactive ingredients

propylene glycol, liquid paraffin, stearyl alcohol, cetyl alcohol, sorbitan monostearate, polyoxyethylene cetylether, purified water, methylparaben, propylparaben.

Distributed By Dolgencorp, LLC

100 Mission Ridge

Goodlettsville, TN 37072

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DG ATHLETES FOOT

tolnaftate cream

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:68169-3050

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
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
MINERAL OIL (UNII: T5L8T28FGP)	
STEARYL ALCOHOL (UNII: 2KR89I4H1Y)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
SORBITAN MONOSTEARATE (UNII: NVZ4I0H58X)	
WATER (UNII: 059QF0KO0R)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68169-3050-2	1 in 1 CARTON		
1		28 g in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333C	12/10/2010	

Labeler - TAI GUK PHARM. CO., LTD. (631101656)

Registrant - UNITED EXCHANGE CORP. (840130579)

Establishment

Name	Address	ID/FEI	Business Operations
TAI GUK PHARM. CO., LTD.		631101656	manufacture(68169-3050)

Revised: 12/2010 TAI GUK PHARM. CO., LTD.