

CANESPIES- tolnaftate cream
OPMX 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.

ACTIVE INGREDIENTS

TOLNAFTATE 1%

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.

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 Poison Control Center right away.

WHEN USING THIS PRODUCT AVOID CONTACT WITH EYES.

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, VENTILLATED 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 WEKS. IF CONDITION PERSISTS LONGER CONSULT A DOCTOR
- THIS PRODUCT IS NOT EFFECTIVE ON THE SCALP OR NAILS

INACTIVE INGREDIENTS

CETYL ALCOHOL, LIQUID PARAFFIN, METHYLPARABEN, POLYOXYETHYLNE

CETYLETHER, PROPYLENE GLYCOL, PROPYLPARABEN, PURIFIED WATER, SORBITAN MONOSTEARATE, STEARYL ALCOHOL

OTHER INFORMATION

- STORE AT 15° TO 30°C (59°F TO 86°F)
- LOT NO. & EXP. DATE: SEE BOX OR CRIMP OF TUBE

NDC 69729-610-05

Canespies

Tolnaftate Cream USP, 1%

Mediated Cream
Relieves itching and burning
Cures most Athlete's Foot

Alivia comezón y ardor - Cura la mayor a de las afecciones del Pie de Atleta

Antifungal / Antimicótico **Net Wt. 0.5 oz (14 g)**

Drug Facts		Drug Facts (continued)	
Active ingredient Tolnaftate 1%	Purpose Antifungal	When using this product avoid contact with eyes	
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		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	
Warnings For external use only.		Other information ■ store at 15° to 30°C (59° to 86°F) ■ Lot No. & Exp. Date: See box or crimp of tube.	
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 immediately.		Inactive ingredients Cetyl Alcohol, Liquid Paraffin, Methylparaben, Polyoxyethylene Cetyether, Propylene Glycol, Propylparaben, Purified Water, Sorbitan Monostearate, Stearyl Alcohol	

EXCLUSIVELY DISTRIBUTED BY: OPMX, SAN DIEGO, CA 92154 PH: 619-600-5632 MADE IN INDIA NDC 69729-610-05

CANESPIES

tolnaftate cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69729-610
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)	

MINERAL OIL (UNII: T5L8T28FGP)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
CETETH-10 (UNII: LF9X1PN3XJ)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
WATER (UNII: 059QF0K00R)	
SORBITAN MONOSTEARATE (UNII: NVZ4I0H58X)	
STEARYL ALCOHOL (UNII: 2KR89I4HIY)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69729-610-05	1 in 1 BOX	09/05/2018	
1	NDC:69729-610-01	14 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	09/05/2018	

Labeler - OPMX LLC (029918743)