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

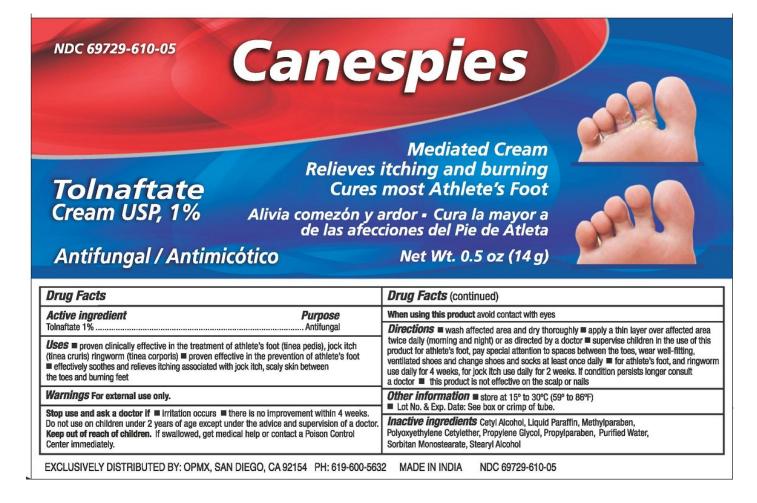
- FOR ATHLETE'S FOOT, AND RINGWORM USE DAILY FOR 4 WEEKS, FOR JOCK ITCH USE DAILY FOR 2 WEKS. IF CONDITION PERSISTS LONGER CONSULT A DOCTOR
- THIS PRODUCT IS NOT EFFECTIVE ON THE SCALP OR NAILS

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



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: 059QF0KO0R)				
SORBITAN MONOSTEARATE (UNII: NVZ 410H58X)				
STEARYL ALCOHOL (UNII: 2KR89I4H1Y)				

F	Packaging						
#	t Item Code	Package Description	Marketing Start Date	Marketing End Date			
1	NDC:69729-610- 05	1 in 1 BOX	07/26/2022				
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	07/26/2022		

Labeler - OPMX LLC (029918743)

Revised: 7/2022 OPMX LLC