

TERPENICOL- undecylenic acid cream
Blaine Labs Inc.

Terpenicol - 601

DRUG FACTS

ACTIVE INGREDIENT

UNDECYLENIC ACID 13%

PURPOSE

ANTIFUNGAL

KEEP OUT OF REACH OF CHILDREN

KEEP OUT OF REACH OF CHILDREN. IF SWALLOWED, GET MEDICAL HELP OR CONTACT A POISON CONTROL CENTER RIGHT AWAY.

INDICATIONS:

CURES ATHLETE'S FOOT (TINEA PEDIS), JOCK ITCH (TINA CRURIS) AND RINGWORM (TINA CORPORIS). RELIEVES ITCHING, BURNING, CRACKING, SCALING, ITCHY, SCALY BETWEEN TOES AND ITCHING, BURNING FEET.

WARNINGS:

DO NOT USE ON CHILDREN UNDER TWO YEARS OF AGE UNLESS DIRECTED BY A PHYSICIAN. FOR EXTERNAL USE ONLY. AVOID CONTACT WITH EYES. IF IRRITATION OCCURS OR IF THERE IS NOT IMPROVEMENT WITHIN FOUR (4) WEEKS (FOR ATHLETE'S FOOT OR RINGWORM) OR WITHIN TWO (2) WEEKS (FOR JOCK ITCH), DISCONTINUE USE AND CONSULT A PHYSICIAN.

DIRECTIONS:

WASH THE AFFECTED AREA WITH SOAP AND WATER AND DRY THOROUGHLY. APPLY A THIN LAYER OF THE PRODUCT OVER AFFECTED AREA TWICE DAILY (MORNING AND NIGHT), OR AS DIRECTED BY A PHYSICIAN. 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 ALHTLETE'S FOOT AND RINGWORM, USE DAILY FOR FOUR (4) WEEKS. FOR JOCK ITCH, USE DAILY FOR TWO (2) WEEKS. IF CONDITION PERSISTS LONGER, CONSULT A PHYSICIAN. WASH HANDS AFTER EACH USE.

INACTIVE INGREDIENTS:

WATER, UREA, HYDROXYETHYLCELLULOSE, DISODIUM EDTA, C12-15 ALKYL BENZOATE, POLYSORBATE 80, SORBITAN LAURATE, CETYL ALCOHOL, GLYCOL STEARATE, PEG-100 STEARATE, LAVANDULA ANGUSTIFOLIA (LAVENDER) OIL, MELALEUCA ALTERNIFOLIA (TEA TREE) LEAF OIL, ALOE BARDADENSIS LEAF JUICE, CLOTRIMAZOLE, TRIETHANOLAMINE, METHYLPARABEN, PROPYLPARABEN

TERPENICOL ANTIFUNGAL CREAM PRODUCT LABEL

DISPENSED EXCLUSIVELY BY PHYSICIANS

NDC-601-01

BLAINE LABS®

**TERPENICOL®
ANTIFUNGAL CREAM**

UNDECYLENIC ACID

37.5 mL (1.25 FL OZ)

BLAINE LABS, INC., 11037 LOCKPORT PLACE,
SANTA FE SPRINGS, CA 90670
(800) 307-8818
31100-P-LBL01 REV20170517

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NDC 63347-601-01



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ANTIFUNGAL CREAM

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TERPENICOL			
undecylenic acid cream			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63347-601
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
UNDECYLENIC ACID (UNII: K3D86KJ24N) (UNDECYLENIC ACID - UNII:K3D86KJ24N)	UNDECYLENIC ACID	4.55 g in 37.5 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
UREA (UNII: 8W8T17847W)	
HYDROXYETHYL CELLULOSE (140 CPS AT 5%) (UNII: 8136Y38GY5)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
SORBITAN MONOLAURATE (UNII: 6W9PS8B71J)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
GLYCOL STEARATE (UNII: 0324G66D0E)	
PEG-100 STEARATE (UNII: YD01N1999R)	
LAVENDER OIL (UNII: ZBP1YXW0H8)	
TEA TREE OIL (UNII: VIF565UC2G)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
CLOTTRIMAZOLE (UNII: G07GZ97H65)	
TROLAMINE (UNII: 9O3K93S3TK)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63347-601-01	37.5 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/19/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M005	06/19/2017	

Labeler - Blaine Labs Inc. (017314571)**Registrant** - Blaine Labs Inc. (017314571)**Establishment**

Name	Address	ID/FEI	Business Operations
Blaine Labs Inc.		017314571	manufacture(63347-601)

