

TERPENICOL ANTIFUNGAL- undecylenic acid liquid
Blaine Labs 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.

ACTIVE INGREDIENT

DRUG FACTS

ACTIVE INGREDIENT

UNDECYLENIC (10-UNDECENOIC) ACID

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 MOST ATHLETE'S FOOT (TINEA PEDIS)
- CURES MOST JOCK ITCH (TINEA CRURIS) AND RELIEVES ITCHING, CRACKING, BURNING AND SCALING, WHICH ACCOMPANY THESE CONDITIONS
- PREVENTS MOST ATHLETE'S FOOT (TINEA PEDIS) WITH DAILY USE

WARNINGS

- DO NOT USE:
- ON CHILDREN UNDER 2 YEARS OF AGE UNLESS DIRECTED BY A PHYSICIAN
- IN OR NEAR THE MOUTH OR THE EYES
- FOR VAGINAL YEAST INFECTIONS

WHEN USING THIS PRODUCT,

AVOID CONTACT WITH THE EYES. IF EYE CONTACT OCCURS, WASH THOROUGHLY WITH WATER.

STOP USE AND CONSULT A PHYSICIAN

IF IRRITATION OCCURS OR IF THERE IS NO IMPROVEMENT WITHIN FOUR (4) WEEKS (FOR ATHLETE'S FOOT OR RINGWORM) OR WITHIN TWO (2) WEEKS (FOR JOCK ITCH)..

DIRECTIONS

- WASH THE AFFECTED AREA WITH SOAP AND WATER, DRY THOROUGHLY, THEN APPLY A HEAVY LAYER OVER THE AFFECTED AREA. USE TWICE DAILY (MORNING

AND NIGHT) OR AS DIRECTED BY A PHYSICIAN

- SUPERVISE CHILDREN IN THE USE OF THIS PRODUCT
- FOR ATHLETE'S: PAY SPECIAL ATTENTION TO SPACES BETWEEN TOES ; WEAR WELL-FITTING, VENTILATED SHOES AND CHANGE SOCKS AT LEAST ONCE, DAILY
- FOR ATHLETE'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

OTHER INFORMATION

- STORE AT ROOM TEMPERATURE

INACTIVE INGREDIENTS OTHER INGREDIENTS

CYMOPHENOL (CARVACROL), UREA, AQUA (WATER), ORGANIC VULGARE (WILD OREGANO) ESSENTIAL OIL, VITIT VINFER (GRAPE) SEED OIL, POLYSORBATE 20, GLYCERYL STEARATE, PROPYLENE GLYCOL, UREA, GLYCERIN, CETYL ALCOHOL, POLYETHYLENE GLYCOL COCOATE, SORBITAN LAURATE, POLYETHYLENE GLYCOL DICOCOATE, POLYETHYLENE GLYCOL, FATTY ACIDS, COCO, LAURETH-4, HYDROXYETHYLCELLULOSE, PHENOXYETHANOL CAPRYLY ALCOHOL, ETHYLHEXYL GLYCERIN, HEXYLENE GLYCOL

TERPENICOL PRODUCT LABEL LABEL BOX

DISPENSED EXCLUSIVELY BY PHYSICIANS

NDC 63347-600-01

BLAINE LABS®

TERPENICOL™

ANTIFUNGAL SOLUTION

10-UNDECENOIC ACID

IN A SOLUTION CONTAINING CYMOPHENOL AND UREA

37.5 mL (1.25 FL OZ)

SEE OPPOSITE PANEL FOR MORE INFORMATION.

*** MADE IN THE U.S.A.**

PLEASE RECYCLE! THIS PACKAGE IS MADE FROM RECYCLABLE MATERIALS.

TEPENICOL ANTIFUNGAL

SOLUTION IS BACKED BY BLAINE LABS®

100 PERCENT, PATIENT-DIRECT, MONEY-BACK GUARANTEE. CALL THE NUMBER BELOW FOR MORE INFORMATION.

QUESTIONS OR COMMENTS?

CALL (800) 307-8818, M-F, 8:00 AM - 5:00 pm (PST)

MANUFACTURED BY:

BLAINE LABS, INC.

11037 LOCKPORT PLACE

SANTE FE SPRINGS, CA 90670

31000-P-BX01

USES: Cures most athlete's foot (tinea pedis), most jock itch (tinea cruris) and most ringworm (tinea corporis).

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 no 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. Keep this and all drugs out of reach of children. In case of accidental ingestion, seek professional assistance or contact a poison control center immediately.

DISPENSED EXCLUSIVELY BY PHYSICIANS

NDC 63347-511-02



TERPENICOL™
ANTIFUNGAL SOLUTION

37.5 mL (1.25 FL OZ)

DIRECTIONS: Wash the affected area with soap and water and dry thoroughly. Apply sparingly 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 athlete's foot and ringworm, use daily for four (4) weeks. For jock itch, use daily for two weeks. If condition(s) persists longer, consult a physician.

Blaine Labs, Inc., Santa Fe Springs, CA 90670
(800) 307-8818
31000-P-LBL01 REV20140114

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| DISPENSED EXCLUSIVELY BY PHYSICIANS | |
| <p>DRUG FACTS</p> <p>ACTIVE INGREDIENT PURPOSE UNDECYLENIC (10-UNDECENOIC) ACID 25% ANTIFUNGAL</p> <p>OTHER INGREDIENTS CYMOPHENOL (CARVACROL), UREA</p> <p>INDICATIONS</p> <ul style="list-style-type: none"> • CURES MOST ATHLETE'S FOOT (TINEA PEDIS) • CURES MOST JOCK ITCH (TINEA CRURIS) AND RELIEVES ITCHING, CRACKING, BURNING AND SCALING, WHICH ACCOMPANY THESE CONDITIONS • PREVENTS MOST ATHLETE'S FOOT (TINEA PEDIS) WITH DAILY USE <p>WARNINGS</p> <ul style="list-style-type: none"> • DO NOT USE: • ON CHILDREN UNDER TWO YEARS OF AGE UNLESS DIRECTED BY A PHYSICIAN • IN OR NEAR THE MOUTH OR THE EYES • FOR VAGINAL YEAST INFECTIONS <p>WHEN USING THIS PRODUCT, AVOID CONTACT WITH THE EYES. IF EYE CONTACT OCCURS, WASH THOROUGHLY WITH WATER.</p> <p>STOP USE AND CONSULT A PHYSICIAN IF IRRITATION OCCURS OR IF THERE IS NO IMPROVEMENT WITHIN FOUR (4) WEEKS (FOR ATHLETE'S FOOT OR RINGWORM) OR WITHIN TWO (2) WEEKS (FOR JOCK ITCH).</p> <p>KEEP OUT OF REACH OF CHILDREN. IF SWALLOWED, GET MEDICAL HELP OR CONTACT A POISON CONTROL CENTER RIGHT AWAY.</p> <p>SEE OPPOSITE PANEL FOR MORE INFORMATION.</p> | <p style="text-align: center;">DISPENSED EXCLUSIVELY BY PHYSICIANS</p> <p style="text-align: right;">NDC 63347-600-01</p> <p style="text-align: center;">BLAINE LABS</p> <p style="text-align: center;">TERPENICOL™ ANTIFUNGAL SOLUTION</p> <p style="text-align: center;">10-UNDECENOIC ACID IN A SOLUTION CONTAINING CYMOPHENOL AND UREA</p> <p>★ MADE IN THE U.S.A.</p> <p>♻️ PLEASE RECYCLE! THIS PACKAGE IS MADE FROM RECYCLABLE MATERIALS.</p> <p>TERPENICOL™ ANTIFUNGAL SOLUTION IS BACKED BY BLAINE LABS® 100 PERCENT, PATIENT-DIRECT, MONEY-BACK GUARANTEE. CALL THE NUMBER BELOW FOR MORE INFORMATION.</p> <p>QUESTIONS OR COMMENTS? CALL (800) 307-8818, M-F, 8:00 AM-5:00 PM (PST)</p> <p>MANUFACTURED BY: BLAINE LABS, INC. 11037 LOCKPORT PLACE SANTA FE SPRINGS, CA 90670</p> <p>31000-P-BX01 REV20140217</p> <p style="text-align: right;">37.5 mL (1.25 FL OZ)</p> |
| DISPENSED EXCLUSIVELY BY PHYSICIANS | |
| <p>DRUG FACTS (CONT)</p> <p>DIRECTIONS</p> <ul style="list-style-type: none"> • WASH THE AFFECTED AREA WITH SOAP AND WATER, DRY THOROUGHLY, THEN APPLY A HEAVY LAYER OVER THE AFFECTED AREA. USE TWICE DAILY (MORNING AND NIGHT) OR AS DIRECTED BY A PHYSICIAN • 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 SOCKS AT LEAST ONCE, DAILY • FOR ATHLETE'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 <p>OTHER INFORMATION</p> <ul style="list-style-type: none"> • STORE AT ROOM TEMPERATURE <p>INACTIVE INGREDIENTS AQUA (WATER), ORIGANUM VULGARE (WILD OREGANO) ESSENTIAL OIL, VITIS VINIFERA (GRAPE) SEED OIL, POLYSORBATE 20, GLYCERYL STEARATE, PROPYLENE GLYCOL, UREA, GLYCERIN, CETYL ALCOHOL, POLYETHYLENE GLYCOL COCCOATE, SORBITAN LAURATE, POLYETHYLENE GLYCOL DICOCCOATE, POLYETHYLENE GLYCOL, FATTY ACIDS, COCO, LAURETH-4, HYDROXYETHYLCELLULOSE, PHENOXYETHANOL, CAPRYLYL ALCOHOL, ETHYLHEXYL GLYCERIN, HEXYLENE GLYCOL</p> | |

TERPENICOL ANTIFUNGAL

undecylenic acid liquid

Product Information

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| Product Type | HUMAN OTC DRUG LABEL | Item Code (Source) | NDC:63347-600 |
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| Route of Administration | TOPICAL | DEA Schedule | | |
| Active Ingredient/Active Moiety | | | | |
| Ingredient Name | Basis of Strength | Strength | | |
| UNDECYLENIC ACID (UNDECYLENIC ACID) | UNDECYLENIC ACID | 25 g in 100 mL | | |
| Inactive Ingredients | | | | |
| Ingredient Name | Strength | | | |
| WATER | | | | |
| OREGANO LEAF OIL | | | | |
| GRAPE SEED OIL | | | | |
| POLYSORBATE 20 | | | | |
| GLYCERYL MONOSTEARATE | | | | |
| PROPYLENE GLYCOL | | | | |
| UREA | | | | |
| GLYCERIN | | | | |
| CETYL ALCOHOL | | | | |
| PEG-7 GLYCERYL COCOATE | | | | |
| SORBITAN MONOLAURATE | | | | |
| POLYETHYLENE GLYCOLS | | | | |
| COCONUT ACID | | | | |
| LAURETH-4 | | | | |
| HYDROXYETHYL CELLULOSE (140 MPAS AT 5%) | | | | |
| PHENOXYETHANOL | | | | |
| CAPRYLIC ALCOHOL | | | | |
| ETHYLHEXYLGLYCERIN | | | | |
| HEXYLENE GLYCOL | | | | |
| Packaging | | | | |
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:63347-600-01 | 37.5 mL in 1 JAR | | |
| Marketing Information | | | | |
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date | |
| OTC monograph final | part333C | 04/01/2014 | | |

Labeler - Blaine Labs Inc. (017314571)

Registrant - Blaine Labs Inc. (017314571)

Establishment

| Name | Address | ID/FEI | Business Operations |
|------|---------|--------|---------------------|
|------|---------|--------|---------------------|

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| Blaine Labs Inc. | | 017314571 | manufacture(63347-600) |
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Revised: 4/2014

Blaine Labs Inc.