

ATHLETES FOOT- undecylenic acid cream
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.

Athletes Foot - 205

DRUG FACTS

Active Ingredient

Undecylenic Acid 25%

Purpose

Antifungal

Keep out of reach of children

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.

INDICATIONS:

Cures Athlete's Foot (Tinea Pedis), Jock Itch (Tinea Cruris) and Ringworm (Tinea Corporis). For effective relief of itching, cracking, burning, and discomfort, which can accompany these conditions.

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.

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 (2) weeks. If condition persists longer, consult a physician.

INACTIVE INGREDIENTS:

Water, Hydroxyethylcellulose, Aloe Barbadensis (Aloe) Leaf Juice, Urea, Disodium EDTA, Coco Caprylate/Caprata, Polysorbate 60, PEG-100 Stearate, Cetyl Alcohol, Glyceryl Stearate, Stearic Acid, Methylparaben, Propylparaben, Sodium Polyacrylate, Hydrogenated Polydecene, Ultramarines, Menthol, Oregano Oil, Peppermint Oil, Triethanolamine

Athlete's Foot Cream product label

NDC: 63347-205-01

Athlete's Foot Cream

PRACTICE EXCLUSIVE

Undecylenic Acid 25%

Jojoba Bead technology

2.0 FL OZ

Manufactured by: Blaine Labs, Inc., 11037

Lockport Place, Santa Fe Springs, CA 90670

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undecylenic acid cream

Product Information

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|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:63347-205 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|-------------------|--------------------------|
| UNDECYLENIC ACID (UNII: K3D86KJ24N) (UNDECYLENIC ACID - UNII:K3D86KJ24N) | UNDECYLENIC ACID | 14.77 mg in 59.148 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|----------|
| WATER (UNII: 059QF0KO0R) | |
| HYDROXYETHYL CELLULOSE (140 CPS AT 5%) (UNII: 8136Y38GY5) | |
| ALOE VERA LEAF (UNII: ZY81Z83H0X) | |
| UREA (UNII: 8W8T17847W) | |
| EDETATE DISODIUM (UNII: 7FLD91C86K) | |
| COCO-CAPRYLATE/CAPRATE (UNII: 8D9H4QU99H) | |
| POLYSORBATE 60 (UNII: CAL22UVI4M) | |
| PEG-100 STEARATE (UNII: YD01N1999R) | |
| CETYL ALCOHOL (UNII: 936JST6JCN) | |
| GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4) | |
| STEARIC ACID (UNII: 4ELV7Z65AP) | |
| METHYLPARABEN (UNII: A2I8C7HI9T) | |
| PROPYLPARABEN (UNII: Z8IX2SC1OH) | |
| SODIUM POLYACRYLATE (2500000 MW) (UNII: 05I15JN12J) | |
| HYDROGENATED POLYDECENE (550 MW) (UNII: U333RI6EB7) | |
| ULTRAMARINE BLUE (UNII: I39WR998BI) | |
| MENTHOL (UNII: L7T10EIP3A) | |
| OREGANO LEAF OIL (UNII: 7D0CGR40U1) | |
| PEPPERMINT OIL (UNII: AV092KU4JH) | |
| TROLAMINE (UNII: 9O3K93S3TK) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:63347-205-01 | 59.148 mL in 1 BOTTLE; Type 0: Not a Combination Product | 04/01/2016 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
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Labeler - Blaine Labs Inc. (017314571)

Registrant - Blaine Labs Inc. (017314571)

Revised: 2/2022

Blaine Labs Inc.