

TINEACIDE PHYSICIAN FORMULA - undecylenic acid cream

TINEACIDE - 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.

Active Ingredients

Undecylenic Acid

Inactive Ingredients

Aloe Vera, Cetyl Alcohol, Clotrimazole, Coco-Caprylate Caprate, Disodium EDTA, Glyceryl Stearate, Hydroxyethylcellulose, Lavender Oil, Methylparaben, PEG-100, Stearate, Polysorbate 60, Propylparaben, Stearic Acid, Tea Tree Oil, Triethanolamine, Urea, Water

Uses

Cures Athlete's Foot (tinea pedis) jock itch (tinea cruris) and ringworm (tinea corporis).

Uses

For effective relief of itching, cracking, burning and discomfort which can accompany these conditions.

Ask Your Physician

Do not use on children under 2 years of age unless directed by a physician

When Using This Product

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 4 weeks. for jock itch use daily for 2 weeks. If condition persists longer, consult a physician.

Warnings

For external use only. Avoid contact with eyes. If irritation occurs or if there is no improvement within 4 weeks (for athlete's foot or ringworm) or within 2 weeks (for jock itch) discontinue use and consult a physician. Keep this and all drugs out of the reach of children. In case of accidental ingestion seek professional assistance or contact a poison control center immediately.

Tineacide Label

Tineacide Antifungal Cream Physician Formula

Dispensed by a physician only.

NDC #63347-500-01

TINEACIDE[®]

**Antifungal
Cream**

NET.WT. 1.25 oz. (35g)

Dr. Blaine's

ACTIVE INGREDIENT: Undecylenic Acid 10%

USES: 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 2 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 4 weeks (for athlete's foot or ringworm) or within 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.

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 4 weeks; for jock itch, use daily for 2 weeks. If condition persists longer, consult a physician.

INACTIVE INGREDIENTS: Aloe Vera, Cetyl Alcohol, Clotrimazole, Coco-Caprylate / Caprate, Disodium EDTA, Glycerol Stearate, Hydroxyethylcellulose, Lavender Oil, Methylparaben, PEG-100 Stearate, Polysorbate 60, Propylparaben, Stearic Acid, Tea Tree Oil, Triethanolamine, Urea, Water.

Blaine Labs, Inc.
Santa Fe Springs, CA 90670
800-307-8818

PNE-TAFL REV. 10/07

NDC #65373-0100-01

TINEACIDE[®]

PHYSICIAN FORMULA

**Antifungal
Cream**

Dispensed by Physician Only

NET.WT. 1.25 oz. (35g)

Blaine Labs

ACTIVE INGREDIENT: Undecylenic Acid 13%

USES: 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 2 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 4 weeks (for athlete's foot or ringworm) or within 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.

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 4 weeks; for jock itch, use daily for 2 weeks. If condition persists longer, consult a physician.

INACTIVE INGREDIENTS: Aloe Vera, Cetyl Alcohol, Clotrimazole, Coco-Caprylate / Caprate, Disodium EDTA, Glycerol Stearate, Hydroxyethylcellulose, Lavender Oil, Methylparaben, PEG-100 Stearate, Polysorbate 60, Propylparaben, Stearic Acid, Tea Tree Oil, Triethanolamine, Urea, Water.

Blaine Labs, Inc.
Santa Fe Springs, CA 90670
800-307-8818

PNE-TAPFPL REV. 10/07

TINEACIDE PHYSICIAN FORMULA

undecylenic acid cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:65373-100
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
UNDECYLENIC ACID (UNII: K3D86KJ24N) (UNDECYLENIC ACID - UNII:K3D86KJ24N)	UNDECYLENIC ACID	13 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
CLOTRIMAZOLE (UNII: G07GZ97H65)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
HYDROXYETHYL CELLULOSE (140 CPS AT 5%) (UNII: 8136Y38GY5)	
ENGLISH LAVENDER OIL (UNII: ZBP1YXW0H8)	
METHYL PARABEN (UNII: A2I8C7HI9T)	
POLYOXYL 100 STEARATE (UNII: YD01N1999R)	
POLYSORBATE 60 (UNII: CAL22UVI4M)	
PROPYL PARABEN (UNII: Z8IX2SC10H)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TEA TREE OIL (UNII: VIF565UC2G)	
TROLAMINE (UNII: 9O3K93S3TK)	
UREA (UNII: 8W8T17847W)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65373-100-01	35.4 g in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333C	01/01/1995	

TINEACIDE

undecylenic acid cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:65373-500
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
UNDECYLENIC ACID (UNII: K3D86KJ24N) (UNDECYLENIC ACID - UNII:K3D86KJ24N)	UNDECYLENIC ACID	10 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
CLOTRIMAZOLE (UNII: G07GZ97H65)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
HYDROXYETHYL CELLULOSE (140 CPS AT 5%) (UNII: 8136Y38GY5)	
ENGLISH LAVENDER OIL (UNII: ZBP1YXW0H8)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
POLYOXYL 100 STEARATE (UNII: YD01N1999R)	
POLYSORBATE 60 (UNII: CAL22UVI4M)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TEA TREE OIL (UNII: VIF565UC2G)	
TROLAMINE (UNII: 9O3K93S3TK)	
UREA (UNII: 8W8T17847W)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65373-500-01	35.4 g in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333C	01/01/1995	

Labeler - Blaine Labs Inc. (017314571)

Registrant - Blaine Labs Inc. (017314571)

Establishment

Name	Address	ID/FEI	Business Operations
Blaine Labs Inc.		017314571	manufacture

Revised: 1/2011

Blaine Labs Inc.