

VITE20- miconazole nitrate liquid
Blaine Labs Inc.

Vite20 - 810

DRUG FACTS

Active Ingredient

Miconazole Nitrate 2%

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), Jock Itch (Tinea Cruris), and Ringworm (Tinea Corporis)
- Relieves Itching, cracking, burning and scaling. which accompany these conditions
- Prevents most Athlete's Foot with daily use

WARNINGS

- For external use only
- Do not use :
 - On children under two (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 contact occurs, rinse 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 sparingly 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 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

Isopropyl Alcohol, Deionized Water, Triethanolamine, Glycerin, Hydroxypropylcellulose, Tocopheryl Acetate, Methylparaben, Ethylparaben, Propylparaben, Butylparaben, Isobutylparaben, Phenoxyethanol

Vite20 product label

VITÉ 20

BRUSH - ON

NDC# 63347-810-01

Vité20®

BRUSH-ON

KILLS FUNGUS

Maxium Strength

Professional Formula

15 mL (0.5 FL OZ)

SEE SIDE PANEL FOR MORE INFORMATION

KILLS FUNGUS

*Made in the U.S.A.

Questions or Comments?

Call 800-307-8818 M-F

7:00 am - 5:00 pm PST

www.vite20.com

Manufactured by:

Blaine Labs, Inc.

11037 Lockport Place

Santa Fe Springs, CA 90670

Please recycle!

This package is made from recyclable materials

06100-p-bx01

VITE20
BRUSH-ON

NDC# 63347-810-01

DRUG FACTS
Active Ingredient: Miconazole Nitrate 2% Purpose: Antifungal

INDICATIONS
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WARNINGS
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• Do not use:
• On children under two (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, rinse 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).

Keep out of reach of children
If swallowed, get medical help or contact a poison control center right away.

SEE SIDE PANEL FOR MORE INFORMATION

DRUG FACTS (cont.)
DIRECTIONS
• Wash the affected area with soap and water, dry thoroughly, then apply sparingly 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 a day.
• 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
Isopropyl Alcohol, Deionized Water, Triethanolamine, Glycerin, Hydroxypropylcellulose, Tocopheryl Acetate, Methylparaben, Ethylparaben, Propylparaben, Butylparaben, Isobutylparaben, Phenoxethanol

Vite20 BRUSH-ON KILLS FUNGUS

Maximum Strength Professional Formula
15 mL (0.5 FL OZ)

KILLS FUNGUS
★ Made in the U.S.A.
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VITE20			
miconazole nitrate liquid			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63347-810
Route of Administration	TOPICAL		
Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
MICONAZOLE NITRATE (UNII: VW4H1CYW1K) (MICONAZOLE - UNII:7NNO0D7S5M)	MICONAZOLE NITRATE	0.30 mg in 15 mL	
Inactive Ingredients			
Ingredient Name	Strength		
ISOPROPYL ALCOHOL (UNII: ND2M416302)			
WATER (UNII: 059QF0KO0R)			
TROLAMINE (UNII: 9O3K93S3TK)			
GLYCERIN (UNII: PDC6A3C0OX)			
HYDROXYPROPYL CELLULOSE, UNSPECIFIED (UNII: 9XZ8H6N6OH)			

.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
ETHYLPARABEN (UNII: 14255EXE39)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
BUTYLPARABEN (UNII: 3QPI1U3FV8)	
ISOBUTYLPARABEN (UNII: 0QQJ25X58G)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63347-810-01	1 in 1 BOX	04/01/2016	
1		15 mL in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M005	04/01/2016	

Labeler - Blaine Labs Inc. (017314571)

Registrant - Blaine Labs Inc. (017314571)

Establishment

Name	Address	ID/FEI	Business Operations
Blaine Labs Inc.		017314571	manufacture(63347-810)

Revised: 12/2023

Blaine Labs Inc.