

ANTIFUNGAL CREAM- antifungal cream
BluePoint Laboratories

2% Miconazole Nitrate Cream, USP

Drug Facts

Active ingredient

Miconazole Nitrate 2%

Purpose

Antifungal

Uses

- For the treatment of most athlete's foot (tinea pedis), jock itch (tinea cruris), Ringworm (tinea corporis).
- For the treatment of superficial skin infections caused by yeast (Candida Albicans)
- Relieves itching, scaling, burning, discomfort and chafing associated with jock itch or itching, burning feet.

Warnings

For external use only

Do not use

- On children under 2 years of age unless directed by a doctor

When using this product

- Avoid contact with the eyes

Stop use and ask a doctor if

- irritation occurs
- there is no improvement within 2 weeks when used for the treatment of jock itch
- there is no improvement within 4 weeks when used for athlete's foot and ringworm

Keep out of reach of children

If swallowed, get medical help or contact a Poison Control Centre right away.

Directions

- Clean the affected area and dry thoroughly.
- Apply a thin layer of the product over affected area twice daily (morning and night) or as directed by a doctor.
- 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 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 doctor.
- This product is not effective on scalp or nails.

Other information

- Do not use if seal on the tube is damaged or is not visible. To open, unscrew cap, pull tab to remove foil seal.
- Store at controlled room temperature.
- Preserve in tight container.
- See crimp of tube or carton for Lot Number and expiry date.

Inactive ingredients

Cetostearyl Alcohol, Chlorocresol, Edetate Disodium, Light Mineral Oil, Macrogol Cetostearyl Ether 20, Propylene Glycol, Purified Water, Sodium Phosphate Dibasic Dihydrate, Sodium Phosphate Monobasic Dihydrate, White Petrolatum.

Questions?

Contact 1-800-707-4621

Manufactured in India by:

Gopaldas Visram and Company Limited.

Plot No. A327, T.T.C. Indl. Area, M.I.D.C.

Mahape, Navi Mumbai - 400710 Mfg. Lic. No.: KD/739

For BluePoint Laboratories

2% Miconazole Nitrate Cream, USP Carton 1oz (28.4g)

Size : L 147.0 x w26.0 x h35.0

<p>Drug Facts</p> <p>Active Ingredient Miconazole Nitrate 2%</p> <p>Purpose Antifungal</p> <p>Uses For the treatment of most athlete's foot (tinea pedis), jock itch (tinea cruris), ringworm (tinea corporis) For the treatment of superficial skin infections caused by yeast (candida albicans) Relieves itching, scaling, burning, discomfort and chafing associated with jock itch or itching, burning feet</p> <p>Warnings For external use only</p>		<p>Drug Facts (continued)</p> <p>Do not use on children under 2 years of age unless directed by a doctor</p> <p>When using this product avoid contact with the eyes</p> <p>Stop use and ask a doctor if Irritation occurs there is no improvement within 2 weeks when used for the treatment of jock itch there is no improvement within 4 weeks when used for athlete's foot and ringworm</p> <p>Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.</p>
<p>Drug Facts (continued)</p> <p>Directions Clean the affected area and dry thoroughly Apply a thin layer of the product over affected area twice daily (morning and night) or as directed by a doctor 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 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</p>		<p>Drug Facts (continued)</p> <p>persists longer, consult a doctor This product is not effective on the scalp or nails</p> <p>Other Information Do not use if seal on the tube is damaged or is not visible. To open, unscrew cap, pull tab to remove foil seal Store at controlled room temperature Preserve in light container See crimp of tube or carton for Lot Number and Expiry Date</p>
<p>NDC: 68001-481-45</p> <p>Antifungal Cream</p> <p>2% Miconazole Nitrate Cream, USP</p> <p>BluePoint LABORATORIES</p> <p>Net Wt. 1 oz (28.4 g)</p>		<p>Manufactured In India by: Gopaldas Verman & Company Limited, Plot No. A387, T.T.C. Indl. Area, M.I.D.C., Mahape, Navi Mumbai - 400710.</p> <p>Mfg. Lic. No.: KD/798</p> <p>For BluePoint Laboratories</p> <p>Rev 10/2021</p>
<p>Drug Facts (continued)</p> <p>Inactive Ingredients Cetostearyl Alcohol, Chloroacresol, Edetate Disodium, Light Mineral Oil, Macrogol Cetostearyl Ether 20, Propylene Glycol, Purified Water, Sodium Phosphate Dibasic Dihydrate, Sodium Phosphate Monobasic Dihydrate, White Petrolatum</p> <p>Questions? Contact 1-800-707-4821</p>		

Unvarnished Area

- 100% PANTONE 293 C
- 100% PANTONE 7434 C
- 100% PANTONE 549 C
- 100% PANTONE Blue 072 C
- 75% Black
- 100% Black

2% Miconazole Nitrate Cream, USP Tube 1oz (28.4g)

130.18mm
(Tube length upto shoulder - 129mm ± 2.0mm)

(Tube Dia - 22mm ± 0.5mm)
73mm

NDC: 68001-481-46

Antifungal Cream

2% Miconazole Nitrate Cream, USP


 Net Wt. 1 oz (28.4 g)

Drug Facts	Drug Facts (continued)	Manufactured in India by: Gopidea Varam & Company Limited, Plot No. A327, T.T.C. Ind. Area, M.I.D.C. Mumbai, New Mumbai - 400710. Mfg. Lic. No.: KD798 For BluePoint Laboratories
Active Ingredient Miconazole Nitrate 2%	Purpose Antifungal	Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away. Other Information - Do not use if seal on the tube is damaged or is not visible. To open, unscrew cap, pull tab to remove foil seal. Store at controlled room temperature as Preserved in tight container as See crimp of tube or carton for Lot Number and Expiry Date.
Uses - For the treatment of most athlete's foot (tinea pedis), jock itch (tinea cruris), ringworm (tinea corporis) - For the treatment of superficial skin infections caused by yeast (candida albicans) Relieves itching, scaling, burning, discomfort and chafing associated with jock itch or itching, burning feet.	Warnings - For external use only Do not use in children under 2 years of age unless directed by a doctor. When using this product avoid contact with the eyes	
Questions? Contact: 1-800-707-4621		Rev 10/2021

- 100% PANTONE 293 C
- 100% PANTONE 7434 C
- 100% PANTONE 549 C
- 100% PANTONE Blue 072 C
- 75% Black
- 100% Black

2% Miconazole Nitrate Cream, USP Carton 0.5oz (14.2g)

Size : L110 x w21 x h28mm

<p>Drug Facts</p> <p>Active Ingredient Miconazole Nitrate 2%</p> <p>Purpose Antifungal</p> <p>Uses For the treatment of most athlete's foot (tinea pedis), jock itch (tinea cruris), ringworm (tinea corporis) For the treatment of superficial skin infections caused by yeast (candida albicans) Relieves itching, swelling, burning, discomfort and chafing associated with jock itch or fishing, burning feet</p> <p>Warnings For external use only</p>		<p>Drug Facts (continued)</p> <p>Do not use on children under 2 years of age unless directed by a doctor</p> <p>When using this product avoid contact with the eyes</p> <p>Stop use and seek a doctor if irritation occurs or there is no improvement within 2 weeks when used for the treatment of jock itch or there is no improvement within 4 weeks when used for athlete's foot and ringworm</p> <p>Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.</p>	
<p>Drug Facts (continued)</p> <p>Directions Clean the affected area and dry thoroughly Apply a thin layer of the product over affected area twice daily (morning and night) or as directed by a doctor 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 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 doctor This product is not effective on the scalp or nails</p>		<p>Drug Facts (continued)</p> <p>Other information Do not use if seal on the tube is damaged or is not visible. To open, unscrew cap, pull tab to remove foil seal Store at controlled room temperature Preserve in tight container See crimp of tube or carton for Lot Number and Expiry Date</p> <p>Inactive Ingredients Cetosteryl Alcohol, Chlorocresol, Edetate Disodium, Light Mineral Oil.</p>	
<p>NDC: 68001-481-48</p> <p>Antifungal Cream</p> <p>2% Miconazole Nitrate Cream, USP</p> <p> Net Wt. 0.5 oz (14.2 g)</p>		<p>Manufactured in India by: Sapadisa Varma & Company Limited, Plot No. A327, T.T.C. Ind. Area, M.I.D.C., Mahape, Navi Mumbai - 400710.</p> <p>Mfg. Lic. No.: KD/739</p> <p>For BluePoint Laboratories Rev 10/2021</p>	
<p>Drug Facts (continued)</p> <p>Macrogl Colosteryl Ether 20, Propylene Glycol, Purified Water, Sodium Phosphate Dibasic Dihydrate, Sodium Phosphate Monobasic Dihydrate, White Petrolatum</p> <p>Questions? Contact 1-800-707-4821</p>			

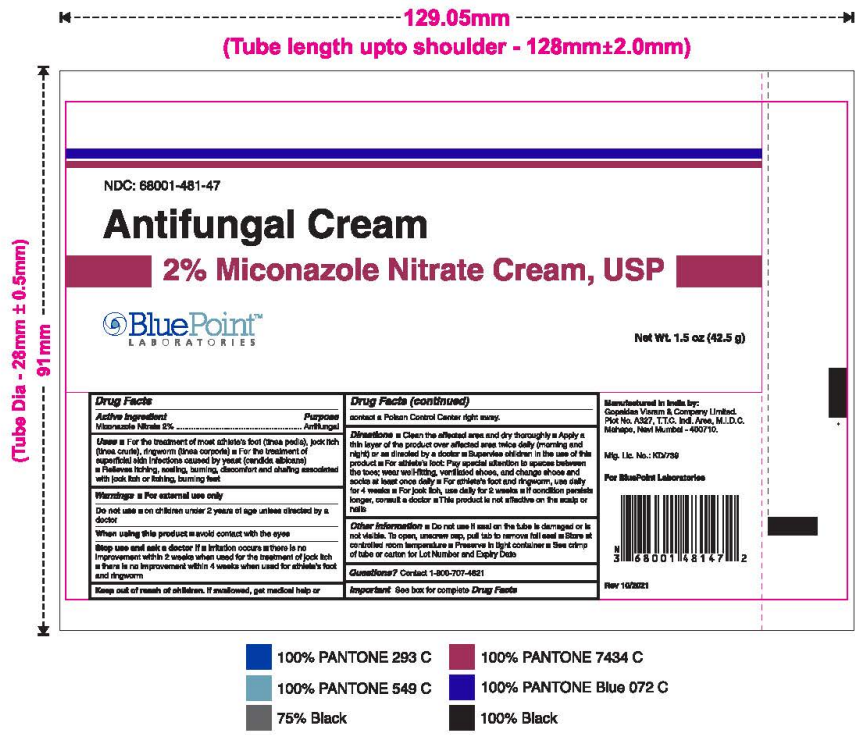
Unvarnished Area

- 100% PANTONE 293 C
- 100% PANTONE 7434 C
- 100% PANTONE 549 C
- 100% PANTONE Blue 072 C
- 75% Black
- 100% Black

2% Miconazole Nitrate Cream, USP Tube 0.5oz (14.2g)



2% Miconazole Nitrate Cream, USP Carton 1.5oz (42.5g)



- 100% PANTONE 293 C
- 100% PANTONE 549 C
- 75% Black
- 100% PANTONE 7434 C
- 100% PANTONE Blue 072 C
- 100% Black

ANTIFUNGAL CREAM			
antifungal cream			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68001-481
Route of Administration	TOPICAL		
Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength
MICONAZOLE NITRATE (UNII: VV4H1CYW1K) (MICONAZOLE - UNII: 7NNO0D7S5M)		MICONAZOLE NITRATE	2 g in 100 g
Inactive Ingredients			
Ingredient Name			Strength
EDETATE DISODIUM (UNII: 7FLD91C86K)			
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)			
LIGHT MINERAL OIL (UNII: N6K5787QVP)			
CHLOROCRESOL (UNII: 36W5307109)			
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)			
WATER (UNII: 059QF0KO0R)			
WHITE PETROLATUM (UNII: B6E5W8RQJ4)			
SODIUM PHOSPHATE DIBASIC DIHYDRATE (UNII: 9425516E2T)			

SODIUM PHOSPHATE, MONOBASIC, DIHYDRATE (UNII: 5QWK665956)

POLYOXYL 20 CETOSTEARYL ETHER (UNII: YRC528SWUY)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68001-481-45	1 in 1 CARTON	12/01/2020	
1		28.4 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:68001-481-47	1 in 1 CARTON	12/01/2020	
2		42.5 g in 1 TUBE; Type 0: Not a Combination Product		
3	NDC:68001-481-48	1 in 1 CARTON	12/01/2020	
3		14.2 g in 1 TUBE; 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	12/01/2020	

Labeler - BluePoint Laboratories (985523874)

Establishment

Name	Address	ID/FEI	Business Operations
Gopaldas Visram & Co., Ltd		858030888	manufacture(68001-481)

Revised: 11/2023

BluePoint Laboratories