

ANTIFUNGAL CREAM- antifungal cream
BluePoint Laboratories

1 % Clotrimazole Cream, USP

Drug Facts

Active ingredient

Clotrimazole 1 %

Purpose

Antifungal

Uses

- For the treatment of most athlete's foot (tinea pedis), jock itch (tinea cruris), ringworm (tinea corporis).
- Relieves itching, scaling, cracking, burning, redness, soreness, irritation, 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 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 or ringworm.

Keep Out Of Reach Of Children

if swallowed, get medical help or contact a Poison Control Center right away.

Directions

- Clean the affected area and dry thoroughly. Apply a thin layer of cream 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 athletes 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.

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 room temperature
- Preserve in tight containers
- See crimp of tube or carton for Lot Number and Expiry Date

INACTIVE INGREDIENTS

Inactive Ingredients: Cetostearyl Alcohol, Methylparaben, Mineral Oil, Polyoxyl 20 Cetostearyl Ether,

Propylene Glycol, Propylparaben, Purified water, White petrolatum

Questions?

Contact 1-800-707-4621

Manufactured in India by:

Gopaldas Visram & 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

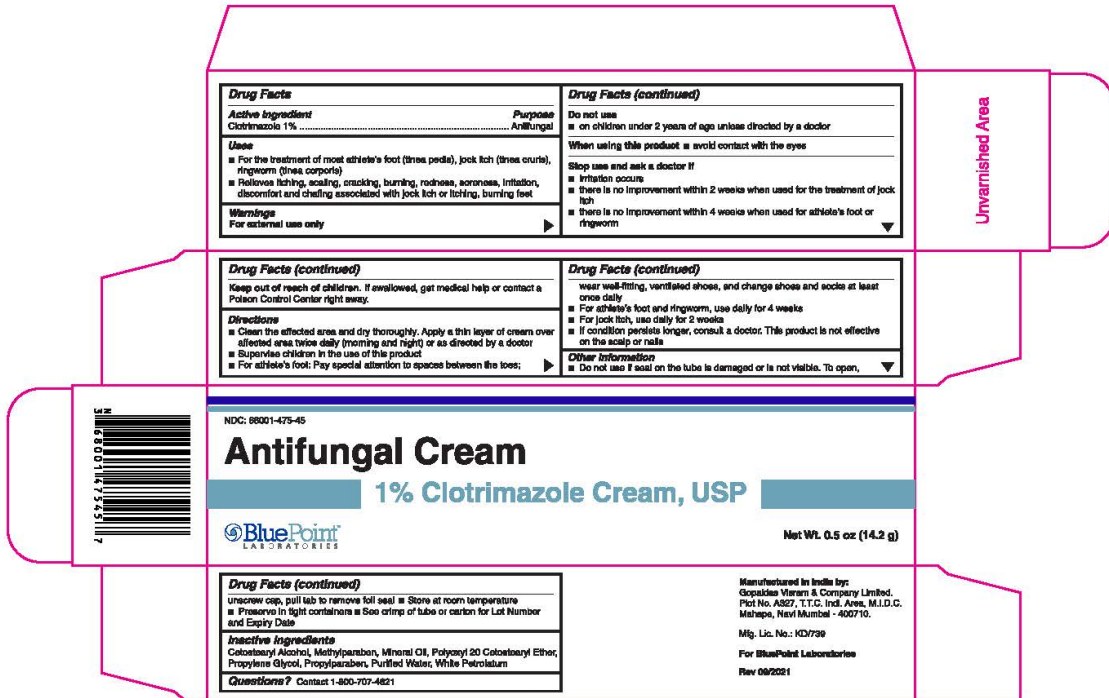
Rev 09/2021

Clotrimazole 1% 0.5oz 68001-475-45



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


Size : L110 x w21 x h28mm



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

Principal Display Panel

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

<p>Drug Facts</p> <p>Active Ingredient Clotrimazole 1% Purpose Antifungal</p> <p>Uses</p> <ul style="list-style-type: none"> For the treatment of most athlete's foot (tinea pedis), jock itch (tinea cruris), ringworm (tinea corporis) Relieves itching, scaling, cracking, burning, redness, soreness, irritation, discomfort and chafing associated with jock itch or itching, burning feet <p>Warnings For external use only</p>		<p>Drug Facts (continued)</p> <p>Do not use</p> <ul style="list-style-type: none"> on children under 2 years of age unless directed by a doctor <p>When using this product ■ avoid contact with the eye</p> <p>Stop use and ask a doctor if</p> <ul style="list-style-type: none"> 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 or ringworm
<p>Drug Facts (continued)</p> <p>Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.</p> <p>Directions</p> <ul style="list-style-type: none"> Clean the affected area and dry thoroughly. Apply a thin layer of cream 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; 		<p>Drug Facts (continued)</p> <p>wear well-fitting, ventilated shoes, and change shoes and socks at least once daily</p> <ul style="list-style-type: none"> 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>Other Information</p> <ul style="list-style-type: none"> Do not use if seal on the tube is damaged or is not visible. To open,
<p>NDC: 68001-475-47</p> <p>Antifungal Cream</p> <p>1% Clotrimazole Cream, USP</p> <p> Net Wt. 1 oz (28.4 g)</p>		
<p>Drug Facts (continued)</p> <p>unscrew cap, pull tab to remove foil seal ■ Store at room temperature</p> <ul style="list-style-type: none"> Preserve in tight containers ■ See crimp of tube or carton for Lot Number and Expiry Date <p>Inactive Ingredients Cetostearyl Alcohol, Methylparaben, Mineral Oil, Polycryl 20 Cetostearyl Ether, Propylene Glycol, Propylparaben, Purified Water, White Petrolatum</p> <p>Questions? Contact 1-800-707-4821</p>		<p>Manufactured in India by: Gopaldas Vissam & Company Limited, Plot No. A327, T.T.C. Indl. Area, M.I.D.C. Mahaape, Navi Mumbai - 400710.</p> <p>Mfg. Lic. No.: KD/739 For BluePoint Laboratories Rev 08/2021</p>

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Clotrimazole 1% 1oz 68001-475-47



ANTIFUNGAL CREAM

antifungal cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68001-475
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CLOTRIMAZOLE (UNII: G07GZ97H65) (CLOTRIMAZOLE - UNII:G07GZ97H65)	CLOTRIMAZOLE	1 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
WATER (UNII: 059QF0KO0R)	
WHITE PETROLATUM (UNII: B6E5W8RQJ4)	
POLYOXYL 20 CETOSTEARYL ETHER (UNII: YRC528SWUY)	
MINERAL OIL (UNII: T5L8T28FGP)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68001-475-47	1 in 1 CARTON	11/25/2020	
1		28.4 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:68001-475-46	1 in 1 CARTON	11/25/2020	06/14/2021
2		15 g in 1 TUBE; Type 0: Not a Combination Product		
3	NDC:68001-475-45	1 in 1 CARTON	11/25/2020	
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	11/25/2020	

Labeler - BluePoint Laboratories (985523874)

Establishment

Name	Address	ID/FEI	Business Operations
Gopaldas Visram & Co., Ltd		858030888	manufacture(68001-475)

Revised: 11/2023

BluePoint Laboratories