

## **ANTIFUNGAL CREAM- antifungal cream**

### **BluePoint Laboratories**

*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.*

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## **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.

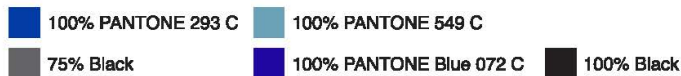
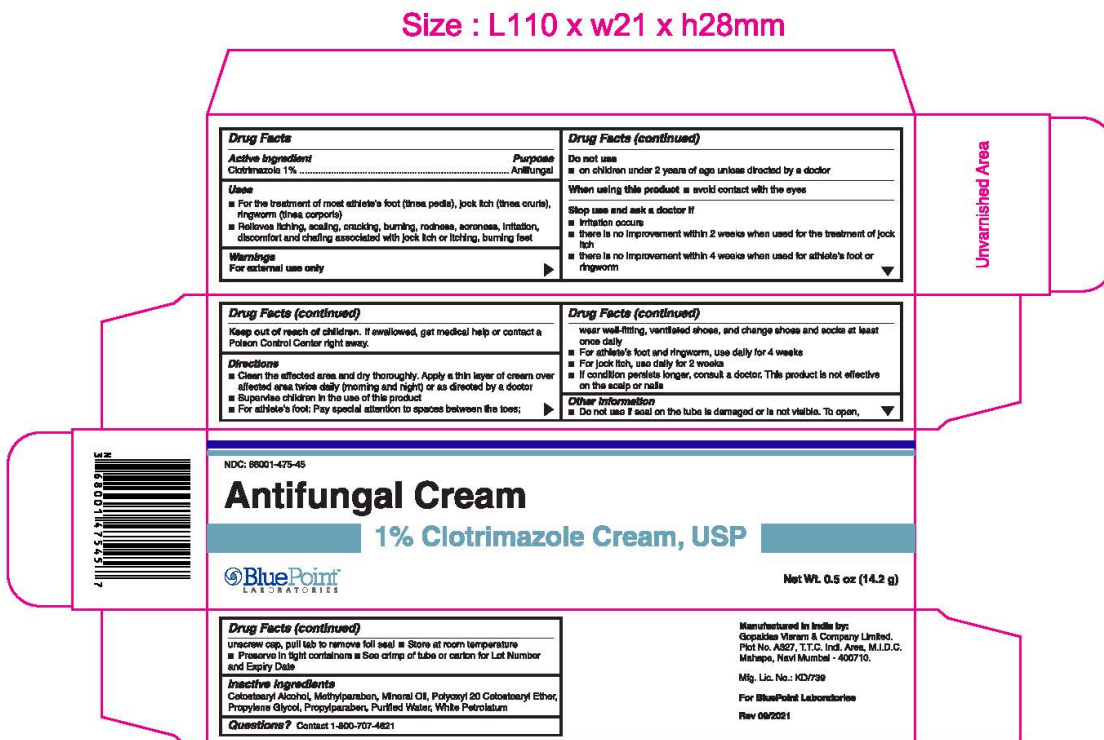
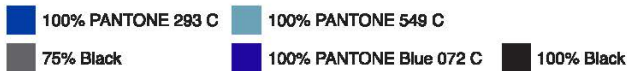
Mahape, Navi Mumbai - 400710.

Mfg. Lic. No.: KD/739

### **For BluePoint Laboratories**

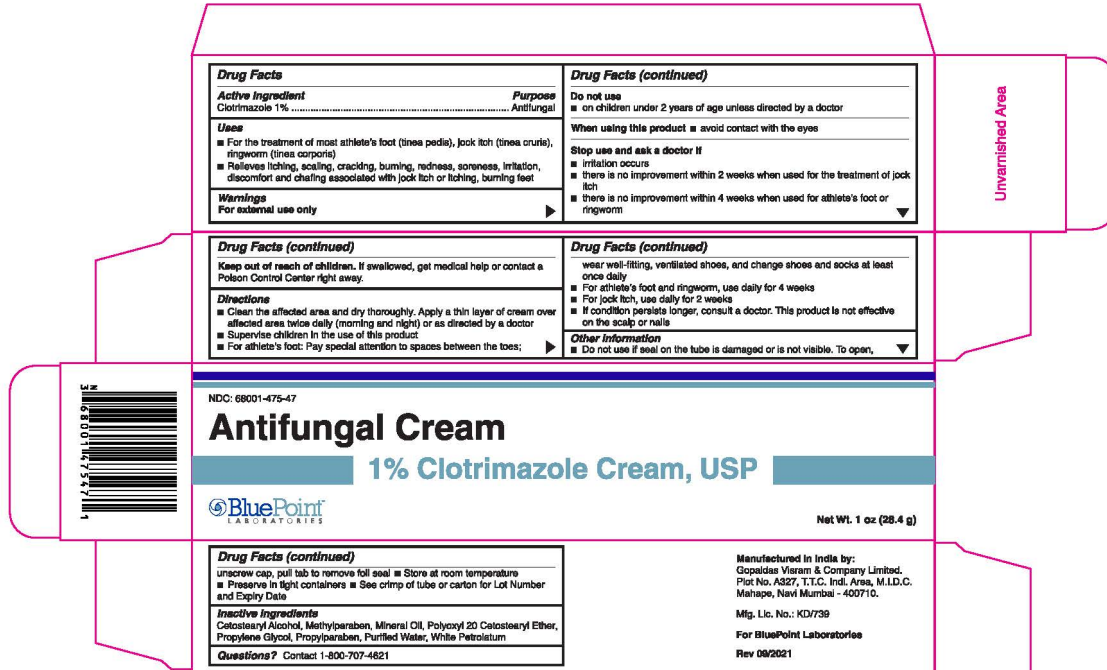
**Rev 09/2021**

Clotrimazole 1% 0.5oz 68001-475-45



# Principal Display Panel

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



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

Clotrimazole 1% 1oz 68001-475-47



## ANTIFUNGAL CREAM

antifungal cream

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:68001-475
<b>Route of Administration</b>	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 final	part333C	11/25/2020	

**Labeler** - BluePoint Laboratories (985523874)

## Establishment

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

Revised: 10/2021

BluePoint Laboratories