ANTIFUNGAL CREAM- antifungal cream
Preferred Pharmaceuticals Inc.

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.

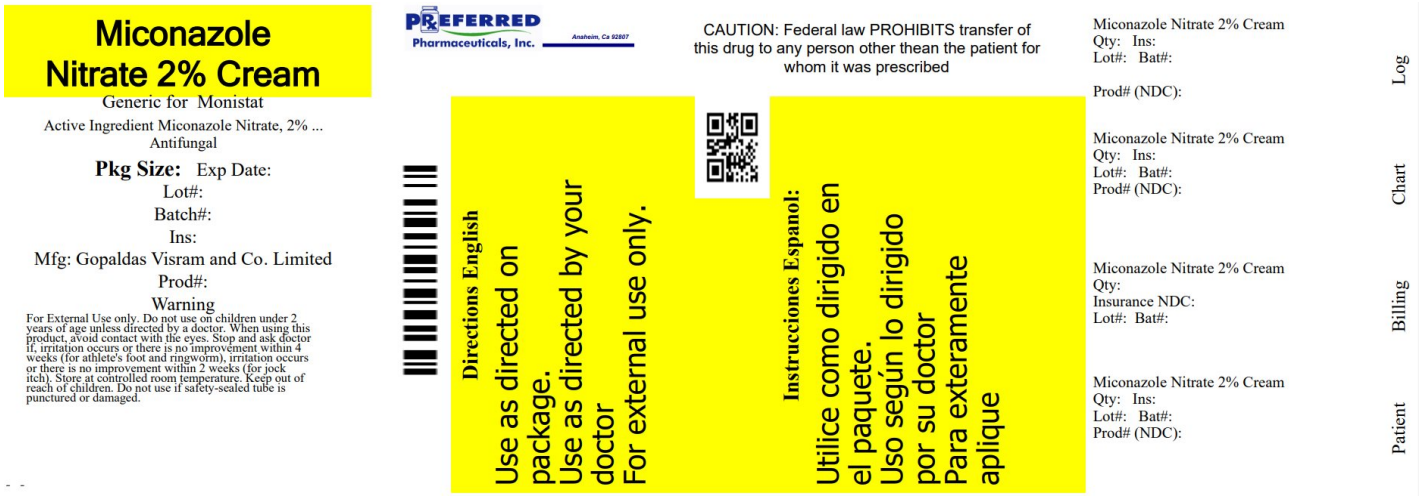
Mahape, Navi Mumbai - 400710 Mfg. Lic. No.: KD/739

For BluePoint Laboratories

Relabeled By: Preferred Pharmaceuticals Inc.

NDC 68788-8645-2

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



ANTIFUNGAL CREAM

antifungal cream

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:68788-8645(NDC:68001-481)
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MICONAZOLE NITRATE (UNII: VW4H1CYW1K) (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: 36W53O7109)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
WHITE PETROLATUM (UNII: B6E5W8RQJ4)	
SODIUM PHOSPHATE, DIBASIC, DIHYDRATE (UNII: 94255I6E2T)	
SODIUM PHOSPHATE, MONOBASIC, DIHYDRATE (UNII: 5QWK665956)	
POLYOXYL 20 CETOSTEARYL ETHER (UNII: YRC528SWJY)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68788-8645-2	1 in 1 CARTON	05/01/2024	
1		28.4 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	05/01/2024	

Labeler - Preferred Pharmaceuticals Inc. (791119022)

Registrant - Preferred Pharmaceuticals Inc. (791119022)

Establishment

Name	Address	ID/FEI	Business Operations
Preferred Pharmaceuticals Inc.		791119022	RELABEL(68788-8645)

Revised: 5/2024 Preferred Pharmaceuticals Inc.