

ANTIFUNGAL- miconazole nitrate cream
PSS World Medical, Inc.

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.

Antifungal Cream

Active Ingredient

Miconazole Nitrate 2%

Purpose

Antifungal

Uses

Treats jock itch, ringworm, and athlete's foot.

☐**INDICATIONS:**☐ Proven clinically effective in the treatment athlete's foot, jock itch and ringworm. Treats superficial skin infections caused by yeast. For effective relief of redness, irritation, itching, and burning.

Warnings

☐**For external use only.**☐

☐**PRECAUTIONS:**☐ For external use only. Not intended for ingestion. Avoid contact with eyes.

Do not use

Do not use on children under 2 years of age unless directed by a doctor.

Stop use and ask a doctor if

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- irritation develops
- there is no improvement within 4 weeks for athlete's foot or ringworm
- or within 2 weeks for jock itch

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.

Directions

☐**Directions**☐

- clean the affected area and dry thoroughly
- apply a thin layer of product over affected area twice daily (morning and night), or as directed by a physician
- supervise children in the use of this product

☐**Athlete's Foot**☐

- pay special attention to the spaces between toes
- wear well-fitting, ventilated shoes and change shoes and socks at least once daily

☐**Athlete's Foot and Ringworm**☐

- use daily for 4 weeks

☐**Jock Itch**☐

- use daily for 2 weeks

This product is not effective on scalp or nails.

Inactive Ingredients

BHT, Cetostearyl Alcohol, Glycerin, Glyceryl Stearate, Methylparaben, Magnesium Aluminum Silicate, Petrolatum, Propylparaben, Polyoxyl 40 Stearate, Purified Water.

Questions

Manufactured for PSS World Medical, Inc.

4345 Southpoint Blvd., Jacksonville, FL 32216

Comments or Questions? 800-777-4908

Made in China

Storage

Store at room temperature 15-30C (59-86F).

Package Label

NDC 68345-817-25

6391 Each

NDC 68345-817-25

REPARA
ADVANCED SKINCARE

ANTIFUNGAL CREAM
2% Miconazole Nitrate

- Indicated for the treatment of jock itch, ringworm, athlete's foot, and superficial skin infections caused by yeast



Store at room temperature 15°C - 30°C (59°F - 86°F)

Manufactured for PSS World Medical, Inc.
4345 Southpoint Blvd, Jacksonville, FL 32216
Comments or Questions? 800-777-4908
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NET WT. 5 oz. (142g)

Reorder # 6391

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FREQUENCY: Apply twice daily, or as directed by a physician.

Drug Facts

Active ingredient	Purpose
Miconazole Nitrate 2%	Antifungal

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REV.00 07/12

6391 Box



ANTIFUNGAL

miconazole nitrate cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68345-817
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MICONAZOLE NITRATE (UNII: VW4H1CYW1K) (MICONAZOLE - UNII:7NNO0D7S5M)	MICONAZOLE NITRATE	20 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
GLYCERIN (UNII: PDC6A3C0OX)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
MAGNESIUM ALUMINUM SILICATE (UNII: 6M3P64V0NC)	
PETROLATUM (UNII: 4T6H12BN9U)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
POLYOXYL 40 STEARATE (UNII: 13A4J4NH9I)	
WATER (UNII: 059QF0K00R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68345-817-25	142 g in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333C	09/05/2012	

Labeler - PSS World Medical, Inc. (101822682)

Registrant - PSS World Medical, Inc. (101822682)

Establishment

Name	Address	ID/FEI	Business Operations
Zhejiang Medicare Pharmaceutical Co., Ltd.		421293835	manufacture(68345-817)

Revised: 9/2012

PSS World Medical, Inc.