MICONAZOLE NITRATE- miconazole nitrate cream
Rebel Distributors Corp

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.

Miconazole Nitrate 2% Cream

Active ingredient

Miconazole nitrate 2%

Purpose

Antifungal

Uses

- proven clinically effective in the treatment of most athlete's foot (tinea pedis), jock itch (tinea cruris) and ringworm (tinea corporis)
- relieves itching, scaling, cracking, burning and discomfort associated with those conditions

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 or if there is no improvement within 4 weeks (for athlete's foot and ringworm)
- irritation occurs or if there is no improvement within 2 weeks (for jock itch)

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 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:

- use daily for 4 weeks. If condition persists longer, consult a doctor.

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

For ringworm, use daily for 4 weeks. If condition persists longer, consult a doctor.

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

- store at 15° - 30°C (59° - 86°F)
- lot number and expiration date: see crimp of tube or see box
- to open: unscrew cap, use pointed end on cap to puncture seal

You may report serious side effects to: *130 Vintage Drive, Huntsville, AL 35811*.

Inactive ingredients

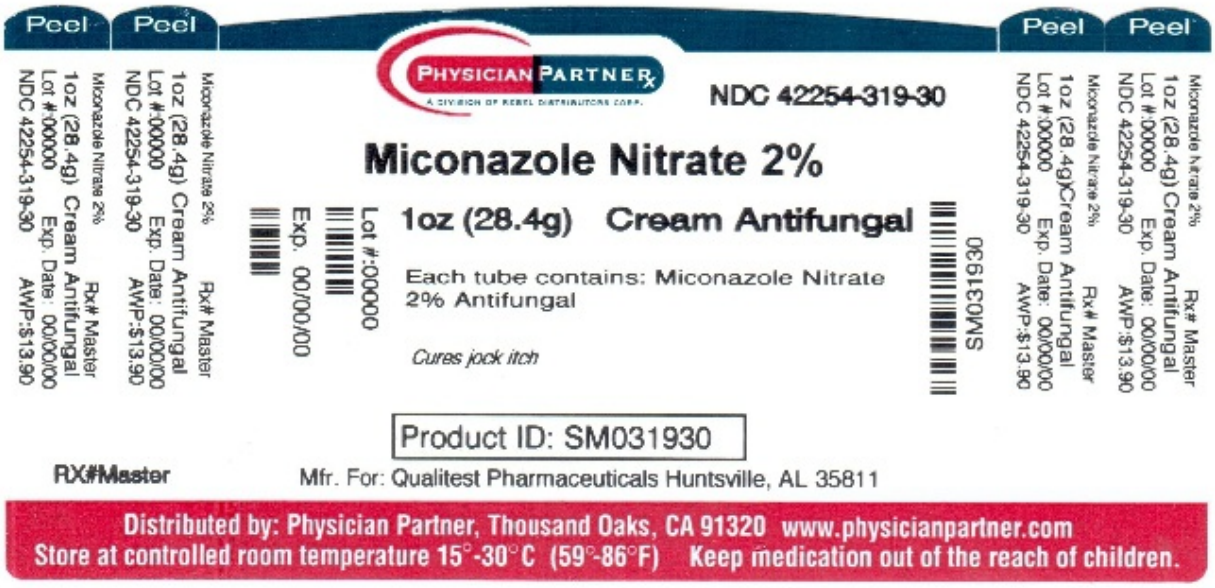
benzoic acid, butylated hydroxyanisole, mineral oil, peglicol 5 oleate, pegoxol 7 stearate, purified water

Made in the **USA**
for Qualitest Pharmaceuticals
Huntsville, AL 35811

Rev. 10/09 R2
8280719 7805

Repackaged by
Rebel Distributors Corp.
Thousand Oaks, CA 91320

PRINCIPAL DISPLAY PANEL



MICONAZOLE NITRATE

miconazole nitrate cream

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:42254-319(NDC:0603-7805)
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**
BENZOIC ACID (UNII: 8SKN0B0MIM)	
BUTYLATED HYDROXYANISOLE (UNII: REK4960K2U)	
MINERAL OIL (UNII: T5L8T28FGP)	
PEG-5 OLEATE (UNII: 0240V77G50)	
PEGOXOL 7 STEARATE (UNII: 3EW5AXE5X5)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:42254-319-30	1 in 1 CARTON		
1		28.4 g in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333C	09/01/2003	

Labeler - Rebel Distributors Corp (118802834)

Registrant - PSS World Medical, Inc. (101822862)

Establishment

Name	Address	ID/FEI	Business Operations
PSS World Medical, Inc.		791528623	REPACK(42254-319)

Establishment

Name	Address	ID/FEI	Business Operations
STAT RX USA LLC		786036330	REPACK(42254-319)

Establishment

Name	Address	ID/FEI	Business Operations
Dispensing Solutions, Inc.		066070785	RELABEL(42254-319) , REPACK(42254-319)

Establishment

Name	Address	ID/FEI	Business Operations
SCRIPT PAK		964420108	RELABEL(42254-319) , REPACK(42254-319)

Establishment

Name	Address	ID/FEI	Business Operations
Keltman Pharmaceuticals, Inc.		362861077	REPACK(42254-319)

Establishment

Name	Address	ID/FEI	Business Operations
Rebel Distirbutors Corp.		118802834	RELABEL(42254-319) , REPACK(42254-319)

Revised: 10/2012 Rebel Distributors Corp