# SECURA ANTIFUNGAL GREASELESS- miconazole nitrate cream SECURA ANTIFUNGAL EXTRA THICK- miconazole nitrate cream Smith & Nephew Medical Ltd

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Secura Antifungal

**DRUG FACTS** 

### **ACTIVE INGREDIENTS**

Miconazole nitrate 2%

### **PURPOSE**

**Antifungal** 

#### **USES**

Antifungal Extra Thick

Cures most jock itch (tinea cruris), ringworm (tinea corporis) and athlete's foot (tinea pedis)

Antifungal Greaseless

Cures most athlete's foot, jock itch and ringworm

### WARNINGS

• For external use only

Do not use on children under 2 years old unless directed by a doctor

- Avoid contact with the eyes
- Stop use and ask a doctor if irritation occurs or if there is no improvement
- Keep reach out of children. In case of ingestion, get medical help or contact a Poison Control Center Immediately.

### **DIRECTIONS**

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

### For athlete's foot:

• pay special attention to the spaces between the toes

- wear well fitting, ventilated shoes
- 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 the scalp or nails.

### **QUESTION OR COMMENTS?**

1 800 876-1261

### **INACTIVE INGREDIENTS**

### SECURA ANTIFUNGAL GREASELESS

allantoin, cetearyl alcohol, polyethylene glycol 1000 cetyl ether, citric acid, diazolidinyl urea, dioctyl adipate, glyceryl stearate, methylparaben, octyl palmitate, octyl stearate, PEG-40 castor oil, petrolatum, o-phenylphenol, propylparaben, sodium cetearyl sulfate, sodium citrate, tocopheryl acetate, water

### SECURA ANTIFUNGAL EXTRA THICK

benzethonium chloride, butylparaben, cellulose gum, cetearyl alcohol, diazolidinyl urea, karaya gum, methylparaben, methyl glucose dioleate, mineral oil, petrolatum, tocopheryl acetate, water, zinc oxide

#### OTHER INFORMATION

### SECURA ANTIFUNGAL EXTRA THICK/SECURA ANTIFUNGAL GREASELESS

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

# PACKAGE LABEL - PRINCIPAL DISPLAY PANEL- SECURA ANTIFUNGAL GREASELESS - TUBE(57g)

Item #59432800

**NDC** 69740-328-00

### **Antifungal Greaseless**

- 2% Miconazole Nitrate
- Cures most jock itch (tinea cruris), ringworm (tinea corporis), and athlete's foot (tinea pedis)
- Relieves burning, itching, scaling, cracking, chafing and redness associated with these conditions
- Pediatric tested
- CHG compatible

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Antifungal Greaseless

### Made in India for:

Smith & Nephew Medical Ltd, 101 Hessle Road, Hull HU3 2BN, England Trademark of Smith & Nephew Certain Marks Reg'd U.S. Pat & Tm. Off.



# PACKAGE LABEL - PRINCIPAL DISPLAY PANEL- SECURA ANTIFUNGAL EXTRA THICK - TUBE(92g)

Item #59432900

### **NDC** 69740-329-00

### **Antifungal Greaseless**

- 2% Miconazole Nitrate
- Cures most jock itch (tinea cruris), ringworm (tinea corporis), and athlete's foot (tinea pedis)
- Relieves burning, itching, scaling, cracking, chafing and redness associated with these conditions
- Pediatric tested
- CHG Compatible
- Can be used on denuded skin

Smith & Nephew

Secura ◊

Antifungal Extra Thick

### Made in India for:

Smith & Nephew Medical Ltd, 101 Hessle Road, Hull, HU3 2BN England Trademark of Smith & Nephew Certain marks Reg'd U.S. Pat & Tm. Off.



# **Drug Facts**

### Active ingredient

Purpose

Miconazole nitrate 2%.

**Antifungal** 

**Uses** Cures most jock itch (tinea cruris), ringworm (tinea corporis) and athlete's foot (tinea pedis)

### Wamings

For external use only

**Do not use** on children under 2 years old unless directed by a doctor

Avoid contact with the eyes

Stop use and ask a doctor if irritation occurs or if there is no improvement

**Keep out of reach of children.** In case of ingestion, get medical help or contact a Poison Control Center immediately

**Directions** ■ clean the affected area and dry thoroughly ■ apply a thin layer of the product over affected area twice daily (morning and night)

supervise children in the use of this product

For athlete's foot: 
pay special attention to the spaces between the toes wear well fitting, ventilated shoes

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 the scalp or nails

**Other information** Store at controlled room temperature 59°F-86°F (15°C-30°C)

Inactive ingredients benzethonium chloride, butylparaben, cellulose gum, cetearyl alcohol, diazolidinyl urea, karaya gum, methylparaben, methyl glucose dioleate, mineral oil, petrolatum, tocopheryl acetate, water, zinc oxide

#### Questions or comments? 1 800 876-1261

Made in India for Smith & Nephew Medical Ltd, 101 Hessle Rd, Hull HU3 2BN England. \*Trademark of Smith & Nephew Certain marks reg'd U.S. Pat. and Tm. Off.

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EE 59432900 NDC 69740-329-00

# Antifungal Extra Thick

### **Antifungal**

- 2% Miconazole Nitrate
- Cures most jock itch (tinea cruris), ringworm (tinea corporis), and athlete's foot (tinea pedis)
- Relieves burning, itching, scaling, cracking, chafing and redness associated with these conditions
- Pediatric tested
- CHG compatible
- Can be used on denuded skin



Antifungal Extra Thick

Net wt. 3.25 oz. (92 g)

Room #

Name

### SECURA ANTIFUNGAL GREASELESS

miconazole nitrate cream

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69740-328	
Route of Administration	TOPICAL			

Active Ingredient/Active Moiety		
Ingredient Name	<b>Basis of Strength</b>	Strength
MICONAZOLE NITRATE (UNII: VW4H1CYW1K) (MICONAZOLE - UNII:7NNO0D7S5M)	MICONAZOLE NITRATE	20 mg in 1 g

Inactive Ingredients			
Ingredient Name	Strength		
ALLANTOIN (UNII: 344S277G0Z)	2 mg in 1 g		
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	0.1 mg in 1 g		
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	2 mg in 1 g		
GLYCERYL MONOSTEARATE (UNII: 2300U9XXE4)	40 mg in 1 g		
METHYLPARABEN (UNII: A2I8C7HI9T)	3 mg in 1 g		
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	3 mg in 1 g		
PETROLATUM (UNII: 4T6H12BN9U)	150 mg in 1 g		
PROPYLPARABEN (UNII: Z8IX2SC1OH)	1.5 mg in 1 g		
SODIUM CETOSTEARYL SULFATE (UNII: 7ZBS06BH4B)	7 mg in 1 g		
SODIUM CITRATE (UNII: 1Q73Q2JULR)	23.5 mg in 1 g		
WATER (UNII: 059QF0KO0R)	594.4 mg in 1 g		
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	109 mg in 1 g		
CETETH-20 (UNII: I835H2IHHX)	10 mg in 1 g		
ETHYLHEXYL PALMITATE (UNII: 2865993309)	8 mg in 1 g		
POLYOXYL 40 CASTOR OIL (UNII: 4ERD2076EF)	14 mg in 1 g		

Ш	Packaging			
# Item Code Package Description		Marketing Start Date	Marketing End Date	
	NDC:69740-328-	57 g in 1 TUBE; Type 0: Not a Combination Product	08/01/2003	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M005	08/01/2003	

### SECURA ANTIFUNGAL EXTRA THICK

### miconazole nitrate cream

<b>Product Information</b>			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69740-329
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	<b>Basis of Strength</b>	Strength
MICONAZOLE NITRATE (UNII: VW4H1CYW1K) (MICONAZOLE - UNII:7NNO0D7S5M)	MICONAZOLE NITRATE	20 mg in 1 g

Inactive Ingredients			
Ingredient Name	Strength		
BENZETHONIUM CHLORIDE (UNII: PH41D05744)	1.3 mg in 1 g		
BUTYLPARABEN (UNII: 3QPI1U3FV8)	0.5 mg in 1 g		
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	2 mg in 1 g		
KARAYA GUM (UNII: 73W9IQY50Q)	70 mg in 1 g		
METHYLPARABEN (UNII: A2I8C7HI9T)	3 mg in 1 g		
MINERAL OIL (UNII: T5L8T28FGP)	40 mg in 1 g		
PETROLATUM (UNII: 4T6H12BN9U)	400 mg in 1 g		
ZINC OXIDE (UNII: SOI2LOH54Z)	300 mg in 1 g		
WATER (UNII: 059QF0KO0R)	21.2 mg in 1 g		
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	2 mg in 1 g		
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	60 mg in 1 g		
CARBOXYMETHYLCELLULOSE (UNII: 05JZ17B19X)	30 mg in 1 g		

l	P	ackaging			
	#	# Item Code Package Description		Marketing Start Date	Marketing End Date
	1	NDC:69740-329- 00	92 g in 1 TUBE; Type 0: Not a Combination Product	08/01/2003	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M005	08/01/2003	

## Labeler - Smith & Nephew Medical Ltd (216344051)

Establishment			
Name	Address	ID/FEI	Business Operations
ENCUBE ETHICALS PVT LTD		725076298	manufacture(69740-328, 69740-329)