

**Thera Antifungal Body- miconazole nitrate powder**  
**McKesson Medical-Surgical 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.*

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**Antifungal Body Powder**

**Active ingredient**

Miconazole Nitrate 2.0%

**Purpose**

Antifungal

**Keep out of reach of children.**

If swallowed, get medical help or contact a Poison Control Center right away.

**Uses**

- for the treatment of 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

**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**

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

**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 the scalp or nails

## Other information

- Protect from freezing. Avoid excessive heat.

## Inactive ingredients

Aleurites Moluccana Seed Oil, Aloe Barbadensis Juice, Bisabolol, Calcium Pantothenate (Vitamin B5), Carthamus Tinctorius (Safflower) Oleosomes, Cellulose, Fragrance, Glycerin, Hydrated Silica, Maltodextrin, Niacinamide (Vitamin B3), Pyridoxine HCL (Vitamin B6), Sodium Ascorbyl Phosphate (Vitamin C), Sodium Bicarbonate, Sodium Hyaluronate, Sodium Starch Octenylsuccinate, Tocopheryl Acetate (Vitamin E), Zea Mays (Corn) Starch, Zingiber Officinale (Ginger) Root Extract

## Principal Display Panel

NDC 68599-0207-3

Thera

Antifungal Body Powder

Helps treat the most common fungal infections including athlete's foot, jock itch and ringworm.

Single Patient Use

Net Weight

3 oz (85 g)

MFR# 53-AFP3

NAME ROOM NO.	<b>Drug Facts</b>	NDC 68599-0207-3	Store at 40-90°F (4-32°C). Questions? Call 1-800-777-4908 Distributed by McKesson Medical-Surgical Inc. Richmond, VA 23233 P/N D0219 Made in USA  6 1 2 4 7 9 2 2 0 2 4 9
	<b>Active ingredient</b> <span style="float: right;"><b>Purpose</b></span>	Miconazole Nitrate 2%..... Antifungal	
	<b>Uses</b> ■ for 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 ■ for treatment of superficial skin infections caused by yeast (Candida albicans)	 <b>ANTIFUNGAL BODY POWDER</b>	
	<b>Warnings</b>	 HELPS PROTECT  HELPS TREAT	
	For external use only. When using this product ■ do not get into eyes	Helps treat the most common fungal infections including athlete's foot, jock itch and ringworm.	
	Stop use and ask a doctor if ■ irritation occurs or if there is no improvement within 4 weeks for athlete's foot or ringworm, or within 2 weeks for jock itch	Single Patient Use	
	Do not use on ■ children under 2 years of age unless directed by a doctor ■ diaper rash	<b>McKesson</b>	
	Keep out of reach of children. If swallowed, get medical help or contact a poison control center right away.	<b>NET WEIGHT 3 oz (85 g)</b> <b>MFR # 53-AFP3</b>	
	<b>Directions</b> ■ Clean the affected area and dry thoroughly ■ Sprinkle 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		
	<b>Athlete's foot</b> ■ Pay special attention to the spaces between toes ■ Wear well-fitting, ventilated shoes and change shoes and socks at least once daily		
<b>Athlete's foot and ringworm</b> ■ Use daily for 4 weeks <b>Jock itch</b> ■ Use daily for 2 weeks. If condition persists longer, consult a doctor.			
This product is not effective on scalp or nails.			
<b>Inactive ingredients</b> Aleurites Moluccana Seed Oil, Aloe Barbadensis Juice, Bisabolol, Calcium Pantothenate (Vitamin B5), Carthamus Tinctorius (Safflower) Oleosomes, Cellulose, Fragrance, Glycerin, Hydrated Silica, Maltodextrin, Niacinamide (Vitamin B3), Pyridoxine HCL (Vitamin B6), Sodium Ascorbyl Phosphate (Vitamin C), Sodium Bicarbonate, Sodium Hyaluronate, Sodium Starch Octenylsuccinate, Tocopheryl Acetate (Vitamin E), Zea Mays (Corn) Starch, Zingiber Officinale (Ginger) Root Extract			

**THERA ANTIFUNGAL BODY**  
miconazole nitrate powder

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:68599-0207
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
MICONAZOLE NITRATE (UNII: VW4HICYW1K) (MICONAZOLE - UNII:7NNO0D7S5M)	MICONAZOLE NITRATE	20 mg in 1 g

**Inactive Ingredients**

<b>Ingredient Name</b>	<b>Strength</b>
CARTHAMUS TINCTORIUS SEED OLEOSOMES (UNII: 9S60Q72309)	
CELLULOSE ACETATE (UNII: 3J2P07GVB6)	
GLYCERIN (UNII: PDC6A3C0OX)	
HYDRATED SILICA (UNII: Y6O7T4G8P9)	
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	
KUKUI NUT OIL (UNII: TP11QR7B8R)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
MALTO DEXTRIN (UNII: 7CVR7L4A2D)	
NIACINAMIDE (UNII: 25X51I8RD4)	
PYRIDOXINE HYDROCHLORIDE (UNII: 68Y4CF58BV)	
SODIUM ASCORBYL PHOSPHATE (UNII: 836SJG51DR)	
.ALPHA.-TOCOPHEROL ACETATE, DL- (UNII: WR1WPI7EW8)	
LEVOMENOL (UNII: 24WE03BX2T)	
HYALURONATE SODIUM (UNII: YSE9PPT4TH)	
STARCH, CORN (UNII: O8232NY3SJ)	
GINGER OIL (UNII: SAS9Z1SVUK)	
CALCIUM PANTOTHENATE (UNII: 568ET80C3D)	

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68599-0207-3	85 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/20/2018	

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333C	09/01/2011	

**Labeler** - McKesson Medical-Surgical Inc. (023904428)**Establishment**

Name	Address	ID/FEI	Business Operations
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Central Solutions		007118524	manufacture(68599-0207)
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Revised: 1/2021

McKesson Medical-Surgical Inc.