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.

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

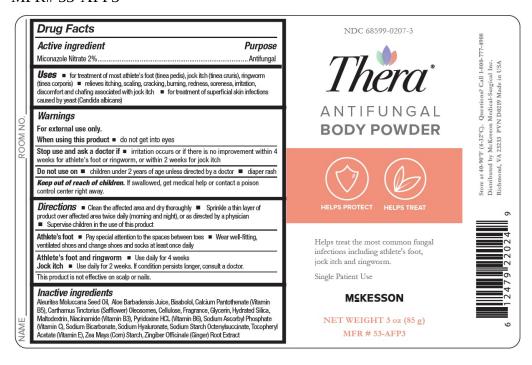
Antifungal Body Powder

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



THERA ANTIFUNGAL BODY

miconazole nitrate powder

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:68599-0207

Route of Administration TOPICAL

Active Ingredient/Active Moiety

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

Inactive Ingredients	
Ingredient Name	Strength
CARTHAMUS TINCTORIUS SEED OLEOSOMES (UNII: 9S60Q72309)	
CELLULOSE ACETATE (UNII: 3J2P07GVB6)	
GLYCERIN (UNII: PDC6A3C0OX)	
HYDRATED SILICA (UNII: Y6O7T4G8P9)	
SODIUM BICARBONATE (UNII: 8 MDF5 V39 QO)	
KUKUI NUT O IL (UNII: TP11QR7B8R)	
ALOE VERA LEAF (UNII: ZY8 1Z8 3H0 X)	
MALTO DEXTRIN (UNII: 7CVR7L4A2D)	
NIACINAMIDE (UNII: 25X51I8RD4)	
PYRIDO XINE HYDRO CHLO RIDE (UNII: 68 Y4CF58 BV)	
SODIUM ASCORBYL PHOSPHATE (UNII: 836 SJG51DR)	
.ALPHATO COPHEROL ACETATE, DL- (UNII: WR1WPI7EW8)	
LEVOMENOL (UNII: 24WE03BX2T)	
HYALURO NATE SO DIUM (UNII: YSE9 PPT4TH)	
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-	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

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Name	Address	ID/FEI	Business Operations

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Central Solutions	0071	18524	manufacture(68599-0207)

Revised: 1/2021 McKesson Medical-Surgical Inc.