

ANTIFUNGAL BODY- miconazole nitrate cream

McKesson

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.

McKesson Antifungal Body Cream

Drug Facts

Active ingredient

Miconazole Nitrate 2%

Purpose

Antifungal

Uses

- 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)

Warnings

- **For External use only.** ☐

☐When using this product

- Do not get into eyes

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.

Do not use on

- children under 2 years of age unless directed by a doctor
- diaper rash

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 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. If condition persists longer, consult a doctor.

This product is not effective on scalp or nails.

Inactive ingredients

Isopropyl Palmitate, Glyceryl Stearate, PEG 100 Stearate, Cyclopentasiloxane, Cetearyl Alcohol, Propylene Glycol, Polyquaternium-37, Propylene Glycol Dicaprylate/Dicaprate, PPG-1 Trideceth-6, Aloe Barbadensis Leaf Juice, Calcium Pantothenate (Vitamin B5), Maltodextrin, Niacinamide (Vitamin B3), Pyridoxine HCL (Vitamin B6), Silica, Sodium Ascorbyl Phosphate (Vitamin C), Sodium Starch Octenylsuccinate, Tocopherol Acetate (Vitamin E), Lysine, Histidine, Arginine, Aspartic Acid, Threonine, Serine, Glutamic Acid, Proline, Glycine, Alanine, Valine, Methionine, Isoleucine, Leucine, Tyrosine, Phenylalanine, Cysteine, Triethanolamine, DMDM Hydantoin, Iodopropynyl Butylcarbamate

McKesson Thera Antifungal Body Cream

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

Single Patient Use

Therapy [for the skin]

Net Contents 4 fl oz (118ml)

MFR# 53-AFC4

<p>NDC 68599-0206-4</p>  <p>Thera™</p> <p>ANTIFUNGAL BODY CREAM</p>  <p>HELPS TREAT</p> <p>Helps treat the most common fungal infections including athlete's foot, jock itch and ringworm.</p> <p>Single Patient Use</p> <p>THERAPY for your skin</p> <p>MCKESSON</p> <p>NET CONTENTS 4 fl oz (118 mL) MFR # 53-AFC4</p>	<p>ROOM NO.</p> <p>NAME</p>	 <p>6 12479 22013 3</p> <p>Drug Facts</p> <table border="1"> <thead> <tr> <th>Active ingredient</th> <th>Purpose</th> </tr> </thead> <tbody> <tr> <td>Miconazole Nitrate 2%</td> <td>Antifungal</td> </tr> </tbody> </table> <p>Uses ■ 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)</p> <p>Warnings ■ For external use only.</p> <p>When using this product ■ do not get into eyes</p> <p>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</p> <p>Do not use on ■ children under 2 years of age unless directed by a doctor ■ diaper rash</p> <p>Keep out of reach of children. If swallowed, get medical help or contact a poison control center right away.</p> <p>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</p> <p>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</p> <p>Athlete's foot and ringworm ■ Use daily for 4 weeks</p> <p>Jock itch ■ Use daily for 2 weeks. If condition persists longer, consult a doctor.</p> <p>This product is not effective on scalp or nails.</p> <p>Inactive ingredients Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Alanine, Aloe Barbadensis Leaf Juice, Arginine, Aspartic Acid, BHT, Calcium Pantothenate (Vitamin B5), Cetyl Alcohol, Cysteine, Dimethicone, DMDM Hydantoin, Glutamic Acid, Glycerin, Glyceryl Stearate, Glycine, Histidine, Iodopropynyl Butylcarbamate, Isoleucine, Isopropyl Palmitate, Leucine, Lysine, Maltodextrin, Methionine, Niacinamide (Vitamin B3), PEG-100 Stearate, Phenylalanine, Proline, Propylene Glycol, Purified Water, Pyridoxine HCL (Vitamin B6), Serine, Silica, Sodium Ascorbyl Phosphate (Vitamin C), Sodium Starch Octenylsuccinate, Stearic Acid, Threonine, Tocopherol Acetate (Vitamin E), Triethanolamine, Tyrosine, Valine (may contain citric acid)</p> <p>Store at 40-90°F (4-32°C). Questions? Call 1-800-777-4908 Distributed by McKesson Medical-Surgical Inc. Richmond, VA 23233 PVN D0620 Made in USA</p>	Active ingredient	Purpose	Miconazole Nitrate 2%	Antifungal
Active ingredient	Purpose					
Miconazole Nitrate 2%	Antifungal					

ANTIFUNGAL BODY

miconazole nitrate cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68599-0206
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MICONAZOLE NITRATE (UNII: VW4H1CYW1K) (MICONAZOLE - UNII:7NNO0D7S5M)	MICONAZOLE NITRATE	2 mg in 100 mL

Inactive Ingredients

Ingredient Name	Strength
CETYL ALCOHOL (UNII: 936JST6JCN)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO)	
ALANINE (UNII: OF5P57N2ZX)	
GLYCERIN (UNII: PDC6A3C0OX)	
WATER (UNII: 059QF0KO0R)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
ALOE (UNII: V5VD430YW9)	
CALCIUM PANTOTHENATE (UNII: 568ET80C3D)	
NIACINAMIDE (UNII: 25X51I8RD4)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM ASCORBYL PHOSPHATE (UNII: 836SJG51DR)	
ALUMINUM STARCH OCTENYLSUCCINATE (UNII: I9PJ0O6294)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
LYSINE (UNII: K3Z4F929H6)	
ARGININE (UNII: 94ZLA3W45F)	
THREONINE (UNII: 2ZD004190S)	
PROLINE (UNII: 9DLQ4CIU6V)	
GLYCINE (UNII: TE7660XO1C)	
VALINE (UNII: HG18B9YRS7)	
METHIONINE (UNII: AE28F7PNPL)	
PHENYLALANINE (UNII: 47E5O17Y3R)	
CYSTEINE (UNII: K848JZ4886)	
DMDM HYDANTOIN (UNII: BYR0546TOW)	
LEUCINE (UNII: GMW67QNF9C)	
TYROSINE (UNII: 42HK56048U)	
TROLAMINE (UNII: 9O3K93S3TK)	
IODOPROPYNYL BUTYLCARBAMATE (UNII: 603P14DHEB)	
ASPARTIC ACID (UNII: 30KYC7MIAI)	
SERINE (UNII: 452VLY9402)	
MALTO DEXTRIN (UNII: 7CVR7L4A2D)	
PYRIDOXINE HYDROCHLORIDE (UNII: 68Y4CF58BV)	
HISTIDINE (UNII: 4QD397987E)	
GLUTAMIC ACID (UNII: 3KX376GY7L)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
ISOPROPYL PALMITATE (UNII: 8CRQ2TH63M)	
PEG-100 STEARATE (UNII: YD01N1999R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68599-0206-4	118 mL in 1 TUBE; Type 0: Not a Combination Product	06/01/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333C	06/01/2017	

Labeler - McKesson (023904428)**Establishment**

Name	Address	ID/FEI	Business Operations
Central Solutions		007118524	manufacture(68599-0206)

Revised: 6/2020

McKesson