

3M CAVILON ANTIFUNGAL- miconazole nitrate cream

3M Health Care

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.

3M Cavilon™ Antifungal Cream

Drug Facts

Active ingredient

Miconazole Nitrate 2%

Purpose

Antifungal

Indications

- Proven clinically effective in the treatment of most athlete's foot (tinea pedis), jock itch (tinea cruris) and ringworm (tinea corporis)
- For the treatment of superficial skin infections caused by yeast (candida albicans)
- For effective relief of redness, irritation, scaling, itching, discomfort and burning

Warnings

- For external use only
- Not intended for ingestion
- Do not use on children under 2 years of age unless directed by a doctor
- Avoid contact with the eyes

- For the treatment of athlete's foot and ringworm: If irritation occurs or if there is no improvement within 4 weeks, discontinue use and consult a doctor
- For the treatment of jock itch: If irritation occurs or there is no improvement within 2 weeks, discontinue use and consult a doctor
- For the prevention of athlete's foot: If irritation occurs, discontinue use and consult a doctor
- Do not use for diaper rash

- Keep out of the reach of children
- If swallow, 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 as directed by a doctor or health care professional
- 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

Inactive ingredients

- Allantoin, Beeswax, Cetyl Dimethicone, Cetyl PEG/PPG-10/1 Dimethicone, Dimethicone, Disodium EDTA, Fragrance, Hydrogenated Castor Oil, Isopropyl Palmitate, Methylparaben, Petrolatum, Propylene Glycol, Propylparaben, Purified Water, Sodium Chloride, Zinc Oxide

Principal Display Panel

LOT

NDC 17518-857-02

3M Cavilon™

Antifungal Cream**Miconazole Nitrate 2%**

- For effective relief of redness, irritation, scaling, itching, discomfort and burning
- Enriched with water-repelling ingredients

REF

3389

Latex-Free

Net Weight 2 oz. • 56 g

Not Made With Natural Rubber Latex

Made in U.S.A. with globally sourced materials for

3M Health Care

2510 Conway Ave.

St. Paul, MN 55144

1-800-228-3957 3M.com/Cavilon

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34-8724-0627-6

EXP ↑

LOT ↑



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3M CAVILON ANTIFUNGAL

miconazole nitrate cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:17518-857
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
miconazole nitrate (UNII: VW4HICYW1K) (miconazole - UNII:7NNO0D7S5M)	miconazole nitrate	2 g in 1000 g

Inactive Ingredients

Ingredient Name	Strength
water (UNII: 059QF0KO0R)	
allantoin (UNII: 344S277G0Z)	
edetate disodium (UNII: 7FLD91C86K)	
sodium chloride (UNII: 451W471Q8X)	
methylparaben (UNII: A218C7H19T)	
propylene glycol (UNII: 6DC9Q167V3)	

petrolatum (UNII: 4T6H12BN9U)	
dimethicone (UNII: 92RU3N3Y1O)	
propylparaben (UNII: Z8IX2SC1OH)	
white wax (UNII: 7G1J5DA97F)	
hydrogenated castor oil (UNII: ZF94AP8MEY)	
zinc oxide (UNII: SOI2LOH54Z)	
isopropyl palmitate (UNII: 8CRQ2TH63M)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:17518-857-02	24 in 1 CASE	11/30/2010	
1		56 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:17518-857-05	12 in 1 CASE	11/30/2010	
2		141 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333C	11/30/2010	

Labeler - 3M Health Care (006173082)

Establishment

Name	Address	ID/FEI	Business Operations
Swiss-American CDMO, LLC		080170933	MANUFACTURE(17518-857)