

**SOOTHE AND COOL TREAT- miconazole nitrate cream**  
**Medline Industries, LP**

*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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**080 INZO Antifungal Cream**

***Active ingredient***

Miconazole Nitrate 2%

***Purpose***

Antifungal

***Uses***

- For the treatment of most athlete's foot (tinea pedis), jock itch (tinea cruris), ringworm (tinea corporis)
- For the treatment of superficial skin infections caused by yeast (candida albicans)
- Relieves most 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 the eyes

**Stop use and ask a doctor**

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

**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 over affected area twice daily or as directed by a physician

- supervise use by children
- 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 four weeks
- for jock itch, use daily for two weeks
- if condition persists longer, consult a doctor
- this product is not effective on scalp or nails

### ***Other information***

- Protect from freezing. Avoid excessive heat.

### ***Inactive ingredients***

allantoin, bees wax, cetyl dimethicone, cetyl PEG/PGG-10/1 dimethicone, dimethicone, fragrance, hydrogenated castor oil, imidazolidinyl urea, isopropyl palmitate, petrolatum, polymethoxy bicyclic oxazolidine, sodium chloride, water, zinc oxide

### **Manufacturing Information**

Manufactured for Medline Industries, LP

Three Lakes Drive, Northfield, IL 60093 USA

Made in USA

[www.medline.com](http://www.medline.com)

1-800-MEDLINE (633-5463)

REF: MSC095635

V1 RH22SAP

### **Package Label**



NDC: 53329-080-57

# SOOTHE & COOL® INZO® Antifungal Cream

Miconazole Nitrate 2%

- + Treats most common fungal infections
- + CHG Compatible
- + Hypoallergenic



5 fl oz  
(148 mL)

REF MSC095635

## Drug Facts

Active ingredient	Purpose
Miconazole Nitrate 2.0%	Antifungal

**Uses** ■ for the treatment of most athlete's foot (tinea pedis), jock itch (tinea cruris) and ringworm (tinea corporis) ■ for the treatment of most superficial skin infections caused by yeast (candida albicans) ■ relieves most 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 doctor

**When using this product** ■ avoid contact with the eyes

**Stop use and ask a doctor** ■ if irritation occurs ■ there is no improvement within 4 weeks for athlete's foot and ringworm ■ there is no improvement within 2 weeks for jock itch

**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 over affected area twice daily or as directed by a physician ■ supervise use by children ■ 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 four weeks ■ for jock itch, use daily for two weeks ■ if condition persists longer, consult a doctor ■ this product is not effective on scalp or nails

### Other information

■ protect from freezing. Avoid excessive heat.

**Inactive ingredients** allantoin, beeswax, cetyl dimethicone, cetyl peg/ppg-10/1 dimethicone, dimethicone, fragrance, hydrogenated castor oil, imidazolidinyl urea, isopropyl palmitate, petrolatum, polymethoxy bicyclic oxazolidine, sodium chloride, water, zinc oxide.

REF MSC095635

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[www.medline.com](http://www.medline.com) 1-800-MEDLINE V1 RH22SAP



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## SOOTHE AND COOL TREAT

miconazole nitrate cream

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:53329-080
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>MICONAZOLE NITRATE</b> (UNII: VW4H1CYW1K) (MICONAZOLE - UNII: 7NNO0D7S5M)	MICONAZOLE NITRATE	20 mg in 100 g

### Inactive Ingredients

Ingredient Name	Strength
<b>CETYL DIMETHICONE 25</b> (UNII: U4AS1BW4ZB)	
<b>5-HYDROXYMETHYL(METHYLENEOXY)-1-AZA-3,7-DIOXABICYCLO(3,3,0)OCTANE</b> (UNII: 82EKS47IC5)	
<b>ALLANTOIN</b> (UNII: 344S277G0Z)	
<b>YELLOW WAX</b> (UNII: 2ZA36H0S2V)	
<b>HYDROGENATED CASTOR OIL</b> (UNII: ZF94AP8MEY)	
<b>DIMETHICONE</b> (UNII: 92RU3N3Y1O)	
<b>ISOPROPYL PALMITATE</b> (UNII: 8CRQ2TH63M)	
<b>PETROLATUM</b> (UNII: 4T6H12BN9U)	
<b>SODIUM CHLORIDE</b> (UNII: 451W47IQ8X)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>ZINC OXIDE</b> (UNII: SOI2LOH54Z)	
<b>CETYL PEG/PPG-10/1 DIMETHICONE (HLB 2)</b> (UNII: V2W71V8T0X)	
<b>IMIDUREA</b> (UNII: M629807ATL)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53329-080-57	141 g in 1 TUBE; Type 0: Not a Combination Product	01/01/2007	
2	NDC:53329-080-58	56 g in 1 TUBE; Type 0: Not a Combination Product	01/01/2007	04/30/2025

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	M005	01/01/2007	

**Labeler** - Medline Industries, LP (025460908)

**Registrant** - Medline Industries, LP (025460908)

Revised: 8/2023

Medline Industries, LP