

**DERMASANA- miconazole nitrate cream**  
**OMG Medical Group, LLC**

*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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**DermaSana**

**Warnings**

do not used on children under two years of age except under the advice and supervision of a doctor  
stop use and ask a doctor if irritation occurs, if conditions worsens, or there is not improvement within four weeks.

for external use only

avoid contact with eyes, scalp, vagina, penis, scrotum and anus

do not ingest

do not use on open wounds

in case of accidental ingestion contact a physician, emergency medical

do not use if you are known to be sensitive to any of the ingredients in this product

**active ingredient**

miconazole nitrate 2% USP

triclosan 0.3% USP

**purpose**

topical antifungal

topical antibacterial

Keep this and all medications our of the reach of children

**directions**

shake well before using

clean and dry affected areas

apply twice per day or as recommended by your doctor

with the brush applicator a thin layer of the product to the affected areas

**uses**

antifungal drying agent

antibacterial drying agent

is indicated in the treatment of most fungi

athlete's foot (tinea pedis)

ringworm (tinea corporis)

jock itch (tinea cruris)

candida albicans

trichophyton rubrum

malassezia furfur

trichophyton mentagrophytes

epidemophyton floccsum

is indicated for the treatment of most bacteria

gram positive bacteria (such as staphylococcus aureus)

is indicated for certain methicillin resistant staphylococcus aureus (MRSA) isolates

is indicated for most coagulase-negative staphylococci

beta hemolytic streptococci

corynebacterium species

clostridium species

anaerobic gram-negative bacilli (such as bacteriodes fragilis)

#### **other information**

store at controlled room temperature 15-30 degrees celcius (59-86 degrees farenhight)

protect from heat

keep from freezing, if freezing occurs, thaw out at room temperature and shake well to mix contents  
back to a solution

acetic acid, aqua (deionized water), benzyl alcohol, c13-14 isoparaffin, ethylhexylglycerin, laureth 7,  
parfum, phenoxyethanol, polyacrylamide, polysorbate 20, sd-alcohol 40B

NDC 55992-XXX-XX

# DermaSana™

(miconazole nitrate 2%, triclosan 0.3%)  
TOPICAL ANTIFUNGAL / ANTIBACTERIAL

**FOR TOPICAL USE ONLY**  
net vol. 1 fl. Oz. (29.57 mL)

DermaSana™

Distributed by:  
**OMG MEDICAL  
GROUP, LLC**  
Miami, FL 33131  
Exp:  
Lot:

### Drug Facts

Active Ingredient	Purpose
Miconazole nitrate 2% USP	Topical Antifungal
Triclosan 0.3% USP	Topical Antibacterial

**Uses** eliminates fungal infections

- antifungal drying agent
- antibacterial drying agent
- is indicated in the treatment of most fungi ■ athlete's foot (tinea pedis)
- ringworm (tinea corporis) ■ jock itch (tinea cruris) ■ candida albicans
- trichophyton rubrum ■ malassezia furfur ■ trichophyton mentagrophytes
- epidermophyton floccosum
- is indicated for the treatment of most bacteria
- gram positive bacteria (such as staphylococcus aureus)
- is indicated for certain methicillin-resistant saphylococcus aureus (MRSA) isolates
- is indicated for most coagulase-negative staphylococci
- beta-hemolytic streptococci ■ cornebacterium species

### Drug Facts (continued)

**Uses (continued)**

- clostridium species
- anaerobic gram-negative bacilli (such as bacteroides fragilis)

**Warnings**

- do not use on children under two years of age except under the advice and supervision of a doctor
- **Stop use and ask a doctor** if irritation occurs, if condition worsens, or there is not improvement within four weeks
- for external use only
- avoid contact with eyes, scalp, vagina, penis, scrotum and anus
- do not ingest
- do not use on open wounds

**KEEP THIS AND ALL MEDICATIONS OUT OF THE REACH OF CHILDREN**

- in case of accidental ingestion, contact a physician, emergency medical
- do not use if you are known to be sensitive to any of the ingredients in this product

### Drug Facts (continued)

**Directions**

- shake well before using ■ clean and dry affected areas
- apply twice per day, or as recommended by your doctor, with the brush applicator, a thin layer of the product to the affected areas

**Other Information**

- store at controlled room temperature 15° – 30° C (59° – 86° F)
- protect from heat
- keep from freezing. If freezing occurs, thaw out at room temperature and shake well to mix contents back to a solution.

**Inactive Ingredients** Acetic Acid, Aqua (Deionized Water), Benzyl Alcohol, C13-14 Isoparaffin, Ethylhexylglycerin, Laureth-7, Parfum (Fragrance), Phenoxyethanol, Polyacrylamide, Polysorbate-20, SD-Alcohol 40B

**Questions or comments?**  
888-259-7737 or visit [www.OMGMEDICALGROUP.com](http://www.OMGMEDICALGROUP.com)

UPC Code

DermaSana™  
Distributed by:  
**OMG MEDICAL  
GROUP, LLC**  
Miami, FL 33131

miconazole nitrate cream

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:55992-023
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MICONAZOLE NITRATE (UNII: VW4HICYW1K) (MICONAZOLE - UNII:7NNO0D7S5M)	MICONAZOLE NITRATE	200 mg in 1 mg
TRICLOSAN (UNII: 4NM5039Y5X) (TRICLOSAN - UNII:4NM5039Y5X)	TRICLOSAN	30 mg in 1 mg

### Inactive Ingredients

Ingredient Name	Strength
ACETIC ACID (UNII: Q40Q9N063P)	
WATER (UNII: 059QF0K00R)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
C13-14 ISOPARAFFIN (UNII: E4F12ROE70)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
LAURETH-7 (UNII: Z95S6G8201)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
POLYACRYLAMIDE (10000 MW) (UNII: E2KR9C9V2I)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
ALCOHOL (UNII: 3K9958V90M)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55992-023-01	200 mg in 1 PACKAGE		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333C	02/14/2013	

**Labeler** - OMG Medical Group, LLC (038837214)

### Establishment

Name	Address	ID/FEI	Business Operations
OMG Medical Group, LLC		038837214	repack(55992-023)

### Establishment

Name	Address	ID/FEI	Business Operations
Pure Source		969241041	manufacture(55992-023)

