## 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 staphyloocccous aureus) is indicated for certain methicillin resistant saphylococcus aureus (MRSA) isolates is indicated for most coagulase-negative staphylococci beta hemolytic streptococci corynebacterium species clostridium species

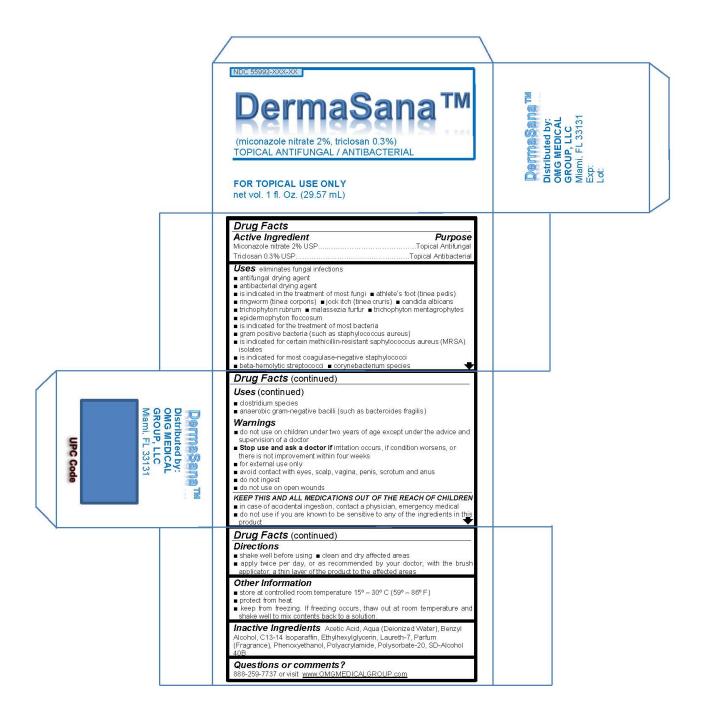
## other information

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



Pro	duct Informati	on							
Proc	luct T yp e		HUMAN OTC DRUG Item Code (Source)			NDC:55	NDC:55992-023		
Rout	e of Administrati	Administration TOPICAL							
Acti	ve Ingredient/	Active Moi	ety						
		Ingi	edient Name			Basis of S	trength	Strength	
MICC	NAZO LE NITRAT	Г <b>Е</b> (UNII: VW4H	I1CYW1K) (MICONAZOL	.E - UNII:7NNO	00D7S5M)	MICONAZOLI	E NITRATE	200 mg in 1 mg	
TRIC	LOSAN (UNII: 4NM	45039Y5X) (TR	ICLOSAN - UNII:4NM503	39 Y5X)		TRICLOSAN		30 mg in 1 mg	
Inac	tive Ingredien	its							
			Ingredient Nam	le				Strength	
	<b>FIC ACID</b> (UNII: Q4								
WATER (UNII: 059QF0KO0R)									
BENZYL ALCOHOL (UNII: LKG8494WBH)									
	14 ISOPARAFFIN (								
	YLHEXYLGLYCER		247K3P)						
	RETH-7 (UNII: Z955		<u>کتر ا</u>						
	NOXYETHANOL (U								
	YACRYLAMIDE (1								
POLYSORBATE 20 (UNII: 7T1F30V5YH)   ALCOHOL (UNII: 3K9958V90M)									
ALCO		30 \$ 3 0 101							
Pac	kaging								
#	Item Code	Pacl	age Description	Marke	ting Start	Date	Marketin	g End Date	
1 ND	C:55992-023-01	200 mg ir	1 PACKAGE						
Ma	rketing Info	rmation							
Mar	keting Category	Applicatio	n Number or Monogr	aph Citation	Marke	ting Start Dat	e Mark	eting End Date	
	monograph final	part333C			02/14/20	10			

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Labeler - OMG Medical Group, LLC (038837214)
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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)

Revised: 3/2013