NAIL MD- 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.

Nail MD

do not use on children under two years of age except under the advce and supervision of a doctor

stop use and ask a doctor if irritation occurs, if condition worsesn, 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

aqua (deionized water), biotin, dimethyl sulfone (msm), ethyoxydiglycol, ethylhexylglycerin, hydrolyzed keratin proteins, hydroxyethylcellulose, phenoxyethanol, polysorbate 20, sd alcohol 40B

miconazole nitrate 2% USP

Topical antifungal

uses

antifungal drying agent

is indicated for candida albicans, trichophyton rubrum, malassezia furfur, trichophyton mentagrophytes

as well as somegram postivie bacteria

lessens the signs of nail dystophy (nail damage caused by trauma or diseas such as fungal infection)

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 making sure to coat both the nail and cuticle completely

other information

store at controlled room temperature 15-30 degrees celsius (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

keep this and all medications out of the reach of children

NAIL MD

miconazole nitrate cream

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:55992-711
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
MICONAZOLE NITRATE (UNII: VW4H1CYW1K) (MICONAZOLE - UNII:7NNO0D7S5M)	MICONAZOLE NITRATE	200 mg in 1 mg

Inactive Ingredients	
Ingredient Name	**Strength**
BIOTIN (UNII: 6SO6U10H04)	
WATER (UNII: 059QF0KO0R)	
DIMETHYL SULFONE (UNII: 9H4PO4Z4FT)	
BIS-ETHOXYDIGLYCOL SUCCINATE (UNII: YGQ120RH3I)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
HYDROXYETHYL CELLULOSE (100 MPA.S AT 2%) (UNII: R33S7TK2EP)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
ALCOHOL (UNII: 3K9958V90M)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55992-711-01	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(55992-711)

Establishment

Name	Address	ID/FEI	Business Operations
Pure Source		969241041	manufacture(55992-711)

Revised: 12/2013 OMG Medical Group, LLC