NAIL MD- tolnafate, triclosan spray
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
(triclosan 0.2%, tolnaftate 1.0%)
ANTIFUNGAL & ANTIBACTERIAL SPRAY

OMG
MEDICAL GROUP

Nail MD®

(triclosan 0.2%, tolnaftate 1.0%)

ANTIFUNGAL & ANTIBACTERIAL SPRAY

Drug Facts

Active Ingredients	*Purpose*
Triclosan 0.2% USP	Antifungal & Antibacterial
Tolnaftate 1.0% USP	Antifungal

Uses eliminates fungus and bacteria in footwear, gloves & clothes
- antifungal and antibacterial drying agent
- prevents spread of fungus and bacteria that may cause infection or disease
- helps to eliminate fungus that may cause nail fungus or athlete's foot

Warnings
- **For use on footwear, gloves & clothes only**
- **For external use only**
- do not use on footware, gloves or clothes of children under two years of age except under the advice and supervision of a doctor
- **Stop use and ask doctor if** irritation occurs, if condition worsens, or there is not improvement within four weeks
- 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
- if ingested accidentally, seek a physician or emergency medical care
- do not use if you are known to be sensitive to any of the ingredients in this product

Directions
- shake well before using
- clean and dry footwear, gloves & clothes
- spray a layer of the product into the footwear, gloves and/or clothes and allow the product to dry before wearing the footwear, gloves and/or clothes
- for athletic or work wear, spray a layer of the product after every use.
- wear well-fitting ventilated footwear, gloves & clothes and change footwear and socks daily
- supervise children in the use of this product

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 Ethylhexylglycerin, Fusidic Acid, Isopropyl Myristate, Phenoxyethanol, SD-Alcohol 40B

Questions or comments?
888-269-7737

Distributed by:
OMG MEDICAL GROUP, LLC
Miami, FL 33176

Nail MD®
(triclosan 0.2%, tolnaftate 1.0%)
ANTIFUNGAL & ANTIBACTERIAL SPRAY

- Use with NAIL MD® Antifungal Nail Lacquer System to help eliminate and prevent nail fungus infections and bacterial infections
- Helps to eliminate the fungus that causes nail fungus and athlete's foot
- Eliminates fungus and bacteria on contact
- Helps to reduce cross-contamination from infected footwear, gloves and clothes by eliminating the fungus and bacteria in those items
- Eliminates odors caused by fungus and bacteria
- Ideal for treating sporting goods and work apparel such as shoes, athletic gear, sports padding, gloves, helmets, gym bags, etc

Directions
- shake well before using
- clean and dry footwear, gloves & clothes
- spray a layer of the product into the footwear, gloves and/or clothes and allow the product to dry before wearing the footwear, gloves and/or clothes
- for athletic or work wear, spray a layer of the product after every use.
- wear well-fitting ventilated footwear, gloves & clothes and change footwear and socks daily
- supervise children in the use of this product

Lot
Exp

Nail MD
ANTIFUNGAL & ANTIBACTERIAL SPRAY

Eliminates fungus and bacteria in shoes, gloves and clothes such as children's shoes, work boots, athletic shoes, athletic gear, gym bags and more.

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NDC 65392-717-01

Nail MD®

(triclosan 0.2%, tolnaftate 1.0%)

ANTIFUNGAL & ANTIBACTERIAL SPRAY

SHOES, GLOVES & CLOTHES SPRAY
ELIMINATES FUNGUS & BACTERIA ON CONTACT
ELIMINATES ODORS ON CONTACT
DRIES CLEAR

ATOMIZADOR ANTIHONGOS Y ANTIBACTERIAL

ATOMIZADOR PARA ZAPATOS, GUANTES Y ROPA
ELIMINA HONGOS Y BACTERIAS AL PUNTO DE CONTACTO
ELIMINA OLORES AL PUNTO DE CONTACTO
SECA TRANSPARENTE

Made in U.S.A.
NET WT. 8 OZ (226 g)

Nail
(triclosan 0.2%, tolr

ATOMIZADOR AN
Y ANTIBACT

- Usar con el Sistema (NAIL MD® Antifung System) para ayuda prevenir infecciones las uñas e infeccion
- Ayuda a eliminar los causan hongos en l atleta
- Elimina hongos y ba de contacto
- Ayuda a reducir la c cruzada de infeccio guantes y ropa con de hongos y bacteri artículos
- Elimina olores caus hongos y bacterias
- Ideal para equipos trabajo como zapat ropas/uniformes, pr deportista, cascos, deportes, etc.

Como Usar
- sacuda la botella ar
- limpie y seque zapa y/o ropa
- atomice una capa d los zapatos, guante permita que el prod antes de usar de nu zapatos, guantes y/
- para los equipos y r deportes o trabajo, capa del producto d cada uso
- usar zapatos, guant a la medida y que te ventilación y cambi los zapatos y media
- supervisar los niños este producto

Nail M
ANTIFUNGAL & ANTIBACT
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NAIL MD

tolnafate, triclosan spray

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:55992-717
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
Triclosan (UNII: 4NM5039Y5X) (TRICLOSAN - UNII:4NM5039Y5X)	Triclosan	20 mg in 1 mg
TOLNAFTATE (UNII: 06KB629TKV) (TOLNAFTATE - UNII:06KB629TKV)	TOLNAFTATE	100 mg in 1 mg

Inactive Ingredients	
Ingredient Name	**Strength**
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
FUSIDIC ACID (UNII: 59XE10C19C)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
ALCOHOL (UNII: 3K9958V90M)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:55992-717-01	100 mg in 1 PACKAGE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	02/14/2013	

Labeler - OMG Medical Group, LLC (038837214)

Establishment

Name	Address	ID/FEI	Business Operations
OMG Medical Group, LLC		038837214	repack(55992-717)

Establishment

Name	Address	ID/FEI	Business Operations
Pure Source		969241041	manufacture(55992-717)