

**ONYCHO-MED- miconazole nitrate, terbinafine hcl
Medhart Pharmaceuticals, Inc.**

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

Onycho-Med

Thank you for choosing Onycho-Med by Medhart Pharmaceuticals, Inc.

To the licensed medical professionals:

“This convenience kit is for prescription compounding only”

Please make sure the kit contains the following components:

Active Ingredients:

1. One **Miconazole Nitrate USP 2% solution in 10ml glass** bottle fitted with a brush cap
2. One glass bottle containing **250 mgs of Terbinafine Hcl USP powder**

In-Active Ingredients:

Acetic Acid, Aqua, Benzyl Alcohol, DMSO, Isopropyl alcohol 70%, Laureth-4, PEG-6, Tea Tree Oil

How supplied:

Onycho-Med is a prescription only convenience kit for compounding by a healthcare professional for topical nail application in management of onychomycosis. The package contains premeasured bottles of Miconazole Nitrate 2% solution * and Terbinafine Hcl USP 250 mg** to make a final volume of 10 ml solution of Miconazole Nitrate 2% and Terbinafine Hcl USP 2.5%.

Indication:

Prescribed for the management of onychomycosis

Mixing Instructions - Easy Two Step Process

- Please check expiration dates listed on the bottles
- Inspect product integrity seals on the bottles inside the carton
- Take the bottles out of the carton and set aside the carton, as illustrated in the picture to the left
- Open the black brush-cap on the Miconazole Nitrate 2% bottle and place it aside for re-use
- Carefully un-screw the white cap from the Terbinafine Hcl 250mg bottle and set aside to discard later
- Carefully pour the contents of the bottle labelled Miconazole Nitrate USP 2% into the bottle labelled Terbinafine Hcl powder 250mg
- Place the black brush-cap on the Terbinafine Hcl 250mg bottle, that now has Miconazole Nitrate USP 2% in it as well and tighten the brush-cap



- Now shake the bottle containing Terbinafine Hcl 250mg USP powder and Miconazole Nitrate USP 2% solution vigorously for 30 seconds
- Make sure the contents have dissolved and there is no residue
- Apply the pharmacy label to the bottle with final solution
- Place the final solution (bottle with black brush cap) back into the carton
- Discard the empty bottle of Miconazole Nitrate 2% and the white cap appropriately
- Please instruct the patient to “shake well before use”



The non-compounded kit has a shelf-life of two years, The final product once mixed will follow a 30 day expiration as per USP 795 BUD (Beyond Use Date) guidelines. Healthcare professionals please follow your local state board of pharmacy BUD guidelines as well. Please discard any unused components of the kit appropriately. Miconazole Nitrate 2% solution meets the requirements for total aerobic microbial count of no more than 100 cfu/gm, as well as for absence of the specified microorganisms Escherichia coli, Pseudomonas aeruginosa, Staphylococcus aureus, Salmonella and Candida albicans.

Storage:

The convenience kit and the compounded product can be stored at room temperature between (15 – 30 °C) and after compounding should be discarded after 30 days as per USP 795 guidelines. Protect from light, protect from freezing.

Onycho-Med compounding kit components have a two-year expiration date ***

For External Use Only: Keep container tightly closed, keep out of reach of children, and avoid contact with eyes.

* This product is not manufactured by Valeant Pharma manufacturers of Fungoid tincture

** Certificate of Analysis on file

***Data and documentation on file

Users are encouraged to report adverse events to FDA MedWatch

1-800-FDA-1088 or at <http://www.fda.gov/Safety/MedWatch/HowToReport/ucm053074.htm>

RX Only

Revised: April2019

Dear professionals we always value your feedback, please email at: suggestions@medhartpharma.com

Manufactured for:

Medhart Pharmaceuticals, Inc.

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PRINCIPAL DISPLAY PANEL

NDC 71150-0786-10

Rx Only

Onycho-Med

(Terbinafine Hcl USP 2.5% and Miconazole Nitrate 2%)

FOR PRESCRIPTION COMPOUNDING ONLY

Topical Antifungal Nail Solution



ONYCHO-MED

miconazole nitrate, terbinafine hcl kit

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:71150-786
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Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71150-786-10	1 in 1 BOX; Type 0: Not a Combination Product	04/16/2019	

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	1 BOTTLE, GLASS	250 mg
Part 2	1 BOTTLE, GLASS	10 mL

Part 1 of 2

TERBINAFINE HYDROCHLORIDE

terbinafine hydrochloride powder, for solution

Product Information

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TERBINAFINE HYDROCHLORIDE (UNII: 012C11ZU6G) (TERBINAFINE - UNII:G7RIW8S0XP)	TERBINAFINE HYDROCHLORIDE	250 mg in 250 mg

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		250 mg in 1 BOTTLE, GLASS; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
UNAPPROVED DRUG OTHER		04/16/2019	

Part 2 of 2

MICONAZOLE NITRATE

miconazole nitrate solution

Product Information

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 10 mL

Inactive Ingredients

Ingredient Name	Strength
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ISOPROPYL ALCOHOL (UNII: ND2M416302)	
ACETIC ACID (UNII: Q40Q9N063P)	
WATER (UNII: 059QF0K00R)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
DIMETHYL SULFOXIDE (UNII: YOW8V9698H)	
LAURETH-4 (UNII: 6HQ855798J)	
POLYETHYLENE GLYCOL 300 (UNII: 5655G9Y8AQ)	
TEA TREE OIL (UNII: VIF565UC2G)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		10 mL in 1 BOTTLE, GLASS; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
UNAPPROVED DRUG OTHER		04/16/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
UNAPPROVED DRUG OTHER		04/16/2019	

Labeler - Medhart Pharmaceuticals, Inc. (080145788)

Revised: 4/2019

Medhart Pharmaceuticals, Inc.