

**DR. LUKE FUNGAL NAIL RENEWAL- fungal nail renewal liquid**  
**Dr.luke Healthcare 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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**83176-006**

**Dr. Luke Fungal Nail Renewal**

**Active Ingredient**

Tolnaftate 1%

**Purpose**

Antifungal Disinfectant Treatment Solution

**Use**

For all caused by nail fungus  
nail discoloration  
nail thickening  
nail splitting  
nail crumbling

**Warnings**

For external use on nail  
fungus(onychomycosis) only, please don't use it on healthy nails  
Don't use it on damaged skin, otherwise, your damaged skin maybe painful.  
For people with severe skin ulceration, please use it with caution.  
Don't drink, avoid contact with your eye  
Children use it under the supervision of adults.  
This product cannot replace medicine.

**Do not use**

Do not use [OTC - DO NOT USE SECTION]  
On damaged skin(cuts, abrasions, eczema, sunburn).  
If you are allergic to any of the ingredients in this product.  
If you are pregnant or breastfeeding.

**WHEN USING SECTION**

fungal infection itching

**STOP USE section**

You are allergic to vinegarsuch as itching, rash swelling of thelips, eyelids, and shortness ofbreath

**ASK DOCTOR**

You are allergic to vinegarsuch as itching, rash swelling of thelips, eyelids, and shortness ofbreath

**KEEP OUT OF REACH OF CHILDREN**

Keep out of reach of children.

**Directions**

Apply it in the day and night(twice a day).

Before using it for the first time.soak the diseased nail withwarm water to soften it, use thenail file to polish the nail, make itthin visibly, and scrape off the dirt on the nail (be careful not tohurt the nail bed), then apply the liquid.

After first use, every 2-3 daysuse the nail file to polish thesurface of the diseased nail andthen continue to use it.

If swallowed, get medical helpor contact a poison controlcenter right away.

**Inactive ingredients**

Water, Acetic Acid, SophoraFlavescens□StelleraChamaejasme Linn., ChineseGolden Larch Bark, FructusCnidii, Crocus Sativus L, Ethanol

**PRINCIPAL DISPLAY PANEL**

83176-006-01



c79 m71 y2 k0  
c78 m11 y45 k0

size: 10\*4.5cm 不干胶工艺: 上光油



印刷工艺:  
1.375g银卡+四色+白  
墨+UV逆向磨砂

2.局部UV



3.局部击凸

FUNGAL NAIL  
RENEWAL

4.局部漏金

# DR. LUKE FUNGAL NAIL RENEWAL

fungal nail renewal liquid

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:83176-006
<b>Route of Administration</b>	TOPICAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>TOLNAFTATE</b> (UNII: 06KB629TKV) (TOLNAFTATE - UNII:06KB629TKV)	TOLNAFTATE	1 mg in 100 mL

## Inactive Ingredients

Ingredient Name	Strength
<b>PSEUDOLARIX AMABILIS BARK</b> (UNII: 49G13A93VE)	
<b>CROCUS SATIVUS WHOLE</b> (UNII: Z5C927G4XF)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>ACETIC ACID</b> (UNII: Q40Q9N063P)	
<b>STELLERA CHAMAEJASME WHOLE</b> (UNII: 80N0P0DD9J)	
<b>ALCOHOL</b> (UNII: 3K9958V90M)	
<b>SOPHORA FLAVESCENS ROOT</b> (UNII: IYR6K8KQ5K)	
<b>CNIDIUM SEED</b> (UNII: V1A3S3CUS)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:83176-006-01	30 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/06/2023	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	M005	04/06/2023	

**Labeler** - Dr.luke Healthcare LLC (118868014)

## Establishment

Name	Address	ID/FEI	Business Operations
Dr.luke Healthcare LLC		118868014	label(83176-006) , manufacture(83176-006)

Revised: 4/2023

Dr.luke Healthcare LLC