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.

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, pleasedon't use it on healthy nails Don't use it on damaged skin,otherwise, your damaged skin maybe painful. For people with severe skinulceration, please use it with caution. Don't drink, avoid contact with your eye Children use it under thesupervision of adults. This product cannot replacemedicine.

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 thedirt 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 the surface of the diseased nail and then continue to use it.

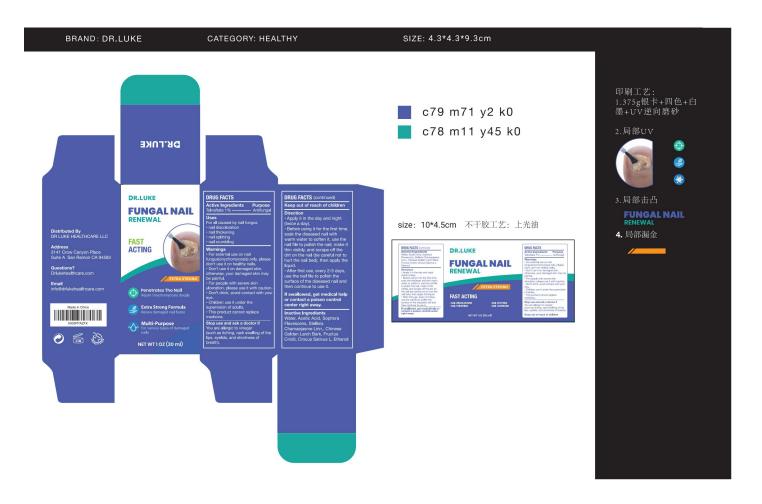
If swallowed, get medical helpor contact a poison controlcenter right away.

Inactive ingredients

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

PRINCIPAL DISPLAY PANEL

83176-006-01



DR. LUKE FUNGAL NAIL RENEWAL

fungal nail renewal liquid

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:83176-006

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name Basis of Strength Strength

TOLNAFTATE (UNII: 06KB629TKV) (TOLNAFTATE - UNII:06KB629TKV) TOLNAFTATE 1 mg in 100 mL

Ingredient Name Strength PSEUDOLARIX AMABILIS BARK (UNII: 49G13A93VE) CROCUS SATIVUS WHOLE (UNII: Z5C927G4XF) WATER (UNII: 059QF0K00R) ACETIC ACID (UNII: Q40Q9N063P) STELLERA CHAMAEJASME WHOLE (UNII: 80N0P0DD9J) ALCOHOL (UNII: 3K9958V90M) SOPHORA FLAVESCENS ROOT (UNII: IYR6K8KQ5K) CNIDIUM SEED (UNII: V1IA3S3CUS)

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