HONGO KILLER NAIL AND FUNGUS- undecylenic acid EFFICIENT LABORATORIES INC

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.

Active Ingredients

Undecylenic Acid 25%

Purpose

Antifungal

Uses

For the cure of most:

- athlete's foot (tinea pedis)
- ringworm (tinea corporis)

For the relief of:

- itching
- burning
- scaling
- cracking
- soreness
- irritation

Warnings

For external use only

Flammable: Keep away from fire or flame.

When using this product: avoid contact with eyes or mucous membranes.

Stop use and ask doctor if:

- irritation occurs
- there is no improvement within 4 weeks

Do not use on children under 2 years of age

Pregnancy or Breast Feeding

If pregnant or breast-feeding, consult a health care professional before using this product

Keep out of Reach of Children

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions

Clean the affected area and dry thoroughly

- Apply a thin layer of Hongo Killer Antifungal Solution over affected area twice daily (morning and night) or as directed by a doctor
- Supervise children in the use of this product.
- For athlete's foot: Pay special attention to spaces between toes; wear well fitting, ventilated shoes, and change shoes and socks at least once daily.
- For athlete's foot and ringworm, use daily for 4 weeks. If condition persists longer, consult a doctor. This product is not effective on scalp or nails.

Questions

Questions or comments?

305-805-3456 (M-F 9:00 am - 5:00 pm EST) www.efficientlabs.com

Inactive ingredients

aloe vera, fragrance, hydroxypropyl methylcellulose, isopropyl alcohol (70% v/v), water, Vitamin E



HONGO KILLER NAIL AND FUNGUS undecylenic acid kit Product Information Product Type HUMAN OTC DRUG Item Code (Source) NDC:58593-301 Packaging # Item Code Package Description Marketing Start Marketing End

NDC:58593-301- 1 in 1 PACKAGE, COMBINATION; Type 1: Convenience Kit of Co-

Date

Quantity of Parts				
Part #	Package Quantity	Total Product Quantity		
Part 1	1 BOTTLE, WITH APPLICATOR	30 mL		
Part 2	1 PACKAGE	30 mL		

Part 1 of 2

HONGO KILLER

undecylenic acid liquid

Product Information

 Item Code (Source)
 NDC:58593-300

 Route of Administration
 TOPICAL

Active Ingredient/Active Moiety

Ingredient NameBasis of StrengthStrengthUNDECYLENIC ACID (UNII: K3D86KJ24N) (UNDECYLENIC ACID - UNII:K3D86KJ24N)UNDECYLENIC ACID | 25 mg in 100 mL

Inactive Ingredients			
Ingredient Name	Strength		
ALOE VERA LEAF (UNII: ZY8 1Z8 3H0 X)			
HYPROMELLOSE 2208 (100 MPA.S) (UNII: B1QE5P712K)			
ISOPROPYL ALCOHOL (UNII: ND2M416302)			
.ALPHATO COPHEROL (UNII: H4N8 55PNZ1)			
WATER (UNII: 059QF0KO0R)			

Packaging				
# Item Code	Package Description	Marketing Start Date	Marketing End Date	
1 NDC:58593- 300-01	30 mL in 1 BOTTLE, WITH APPLICATOR; Type 1: Convenience Kit of Co-Package			

Marketing Information				
Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
part333C				
	Application Number or Monograph Citation	Application Number or Monograph Citation Marketing Start Date		

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HONGO KILLER NAIL

nail creams and lotions

Product Information

ı	Packaging			
ı	# Item Code	Package Description	Marketing Start Date	Marketing End Date
ı	1	30 mL in 1 PACKAGE; Type 1: Convenience Kit of Co-Package		

Marketing Information					
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
Cosmetic					

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	part333c	07/01/2016		

Labeler - EFFICIENT LABORATORIES INC (969044932)

Revised: 2/2020 EFFICIENT LABORATORIES INC