

MYCO NAIL A ANTIFUNGAL SOLUTION- undecylenic acid liquid
Kramer Novis

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.

Myco Nail A
AntiFungal Solution

Drug Facts

Active ingredient

Undecylenic Acid 25% v/v

Purpose

Antifungal

Uses

For the treatment of athlete's foot (tinea pedis), ringworm (tinea corporis). For effective relief of itching, irritation, and burning feet.

Warnings

For external use only. Flammable: Keep away from fire and flame.

Do not use on children under 2 years of age unless directed by a physician.

When using this product avoid contact with the eyes and mucuos membranes.

Stop use and ask a doctor if irritation occurs or is there is no improvement within 4 weeks.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away. If you are pregnant or breast-feeding consult a health care professional before using this product.

Directions

Clean the affected area and dry thoroughly. Apply a thin layer of Myco Nail A over the affected area twice daily (morning and night) or as directed by a physician. Supervise children in the use of this product. For athlete's foot: pay special attention to spaces between toes; wear well-fitted, ventilated shoes, and change shoes and socks at least once daily. Use daily for 4 weeks. If condition persists longer, consult a physcian.

Other information

Store between 15 - 30 C (50 - 86F).

Do not accept if safety seal is broken or missing.

Inactive ingredients

Benzyl acetate, benzyl alcohol, cetylpyridinium chloride, chloroxylenol, eucalyptol, glacial acetic acid, Isopropyl alcohol, propionic acid, propylene glycol, sodium propionate and triacetin.

Questions or comments:

Kramer Novis, San Juan PR, 1-787-767-2072

PRINCIPAL DISPLAY PANEL - 30ml Bottle Carton

Myco Nail A[®]

Antifungal Solution

Topical Formula

1 Fl. Oz. 30 ml.

MANUFACTURED IN USA FOR

KRAMER-NOVIS

San Juan, P.R. 00918

<p>Drug Facts</p> <table border="1"><thead><tr><th>Active Ingredient</th><th>Purpose</th></tr></thead><tbody><tr><td>Undecylenic acid 25%v/v.....</td><td>Antifungal</td></tr></tbody></table> <p>Uses</p> <p>For effective treatment of athlete's foot (tinea pedis) and ringworm (tinea corporis). For effective relief of itching, irritation and burning feet.</p> <p>Warnings</p> <p>For external use only. Flammable: Keep away from fire and flame.</p> <p>Do not use on children under 2 years of age unless directed by a physician.</p> <p>When using this product avoid contact with the eyes and mucous membranes.</p> <p>Stop use and ask a doctor if irritation occurs or if there is no improvement within 4 weeks.</p> <p>Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away. If you are pregnant or breast-feeding consult a health care professional before using this product.</p> <p>This product is not effective on scalp or nails.</p>	Active Ingredient	Purpose	Undecylenic acid 25%v/v.....	Antifungal	<p>NDC 52083-242-30</p> <p>Myco Nail A</p> <p>Antifungal Solution</p> <p>Topical Formula</p> <p>1 Fl. Oz. 30 ml.</p> <p>MANUFACTURED IN USA FOR</p> <p>KRAMER-NOVIS</p> <p>San Juan, PR. 00918</p>	<p>Drug Facts (continued)</p> <p>Directions</p> <p>Clean the affected area and dry thoroughly. Apply a thin layer of Myco Nail A over the affected area twice daily (morning and night) or as directed by a physician. Supervise children in the use of this product. For athlete's foot: pay special attention to spaces between toes; wear well-fitted, ventilated shoes, and change shoes and socks at least once daily. Use daily for 4 weeks. If condition persists longer, consult a physician.</p> <p>Other Information</p> <p>Store between 15 - 30 C (59 - 86F). Do not accept if safety seal is broken or missing.</p> <p>Inactive Ingredients Benzyl acetate, benzyl alcohol, cetylpyridinium chloride, chloroxylenol, eucalyptol, glacial acetic acid, isopropyl alcohol, propionic acid, propylene glycol, sodium propionate and triacetin.</p> <p>Questions or comments:</p> <p>Kramer Novis, San Juan PR, 1-787-767-2072</p>
Active Ingredient	Purpose					
Undecylenic acid 25%v/v.....	Antifungal					

MYCO NAIL A ANTIFUNGAL SOLUTION

undecylenic acid liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:52083-242
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
UNDECYLENIC ACID (UNII: K3D86KJ24N) (UNDECYLENIC ACID - UNII:K3D86KJ24N)	UNDECYLENIC ACID	250 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
BENZYL ACETATE (UNII: 0ECG3V79ZJ)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
CETYLPIRIDINIUM CHLORIDE (UNII: D9OM4SK49P)	
CHLOROXYLENOL (UNII: 0F32U78V2Q)	
EUCALYPTOL (UNII: RV6J6604TK)	
ACETIC ACID (UNII: Q40Q9N063P)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
PROPIONIC ACID (UNII: JHU490RVYR)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SODIUM PROPIONATE (UNII: DK6Y9P42IN)	
TRIACETIN (UNII: XHX3C3X673)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:52083-242-30	1 in 1 CARTON	01/14/2014	
1		30 mL in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part333C	01/14/2014	

Labeler - Kramer Novis (090158395)**Registrant** - Kramer Novis (090158395)

