

BOTANIMEDIX ONYCHORX ANTIFUNGAL NAIL GEL- undecylenic acid gel
Cosco International, 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.

Botanimedix OnychoRX Antifungal Nail Gel

DRUG FACTS

Active Ingredient Purpose

Undecylenic Acid 25%.....Anti-fungal

Uses:

For the cure of most Tinea Pedis (athlete's foot) and Tinea Corporis (ringworm)

For relief of:

Itching, Burning, Redness, Irritation, Scaling, Soreness

Discomfort which may accompany these conditions

Directions:

Apply twice daily for best results.

Warnings:

For external use only.

When using this product

- Do not get into eyes.

Stop use and ask a doctor if:

- Condition worsens.
- Symptoms last more than 7 days or clear and occur again within a few days.

Keep out of reach of children.

- If swallowed, get medical help or contact a Poison Control Center right away.

Inactive Ingredients:

Alpha Tocopheryl Acetate (Vitamin E), Cannabidiol, Cetostearyl Alcohol, Clove Leaf Oil, Dimethyl Sulfoxide, Ethylhexylglycerin, Eucalyptus Oil, Glyceryl Monostearate, Hypromellose, Isopropyl Palmitate, Peppermint Oil, Phenoxyethanol, Polysorbate 60, Propolis Wax, Tea Tree Oil, Urea, Water

Questions?

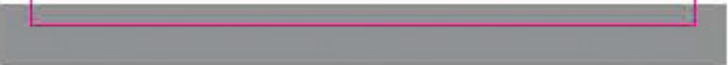
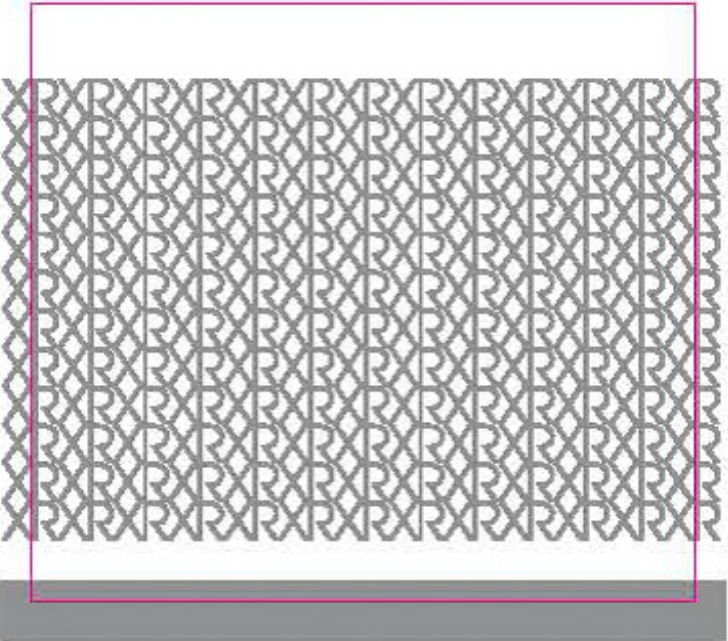
Call: 1-800-964-5406

www.botanimedix.com

Distributed by:

BotaniMedix

Atlanta, GA 30067



DRUG FACTS	
Active Ingredients Undecylenic Acid - 26.5%	Purpose Antifungal
Inactive Ingredients: Alpha Tocopherol Acetate, Vitamin E, Camellidol, Cetylstearyl Alcohol, Clove Leaf Oil, Dimethyl Sulfoxide, Ethylhexylglycerin, Eucalyptus Oil, Glycerol Monostearate, Hyrammellous, Isopropyl Palmitate, Peppermint Oil, Phenoxyethanol, Polyoctadec 60, Propolis Wax, Tea Tree Oil, Urea, Water	
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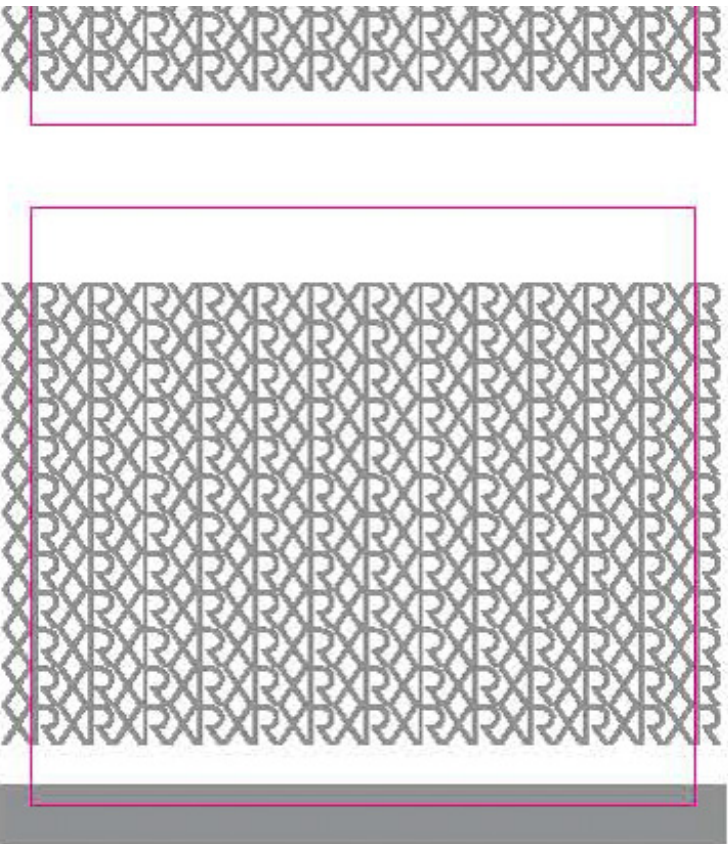
BotaniMedix

— DR. FORMULATED —
— TRIPLE ACTION —
— ANTI-FUNGAL —

OnychorX
Medicated Nail Pen

2ml | 0.067 FL.oz





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Active Ingredients Undecylenic Acid - 25% Inactive Ingredients: Alpha Tocopherol Acetate, Vitamin E ₂ , Cannabidiol, Cestostemyl Alcohol, Clove Leaf Oil, Dimethyl Sulfoxide, Ethylhexylglycerin, Eucalyptus Oil, Glycerol Monostearate, Hyramellolam, Isopropyl Palmitate, Peppermint Oil, Phenoxysthionol, Polysorbate 80, Propolis Wax, Tea Tree Oil, Urea, Water	Purpose Antifungal
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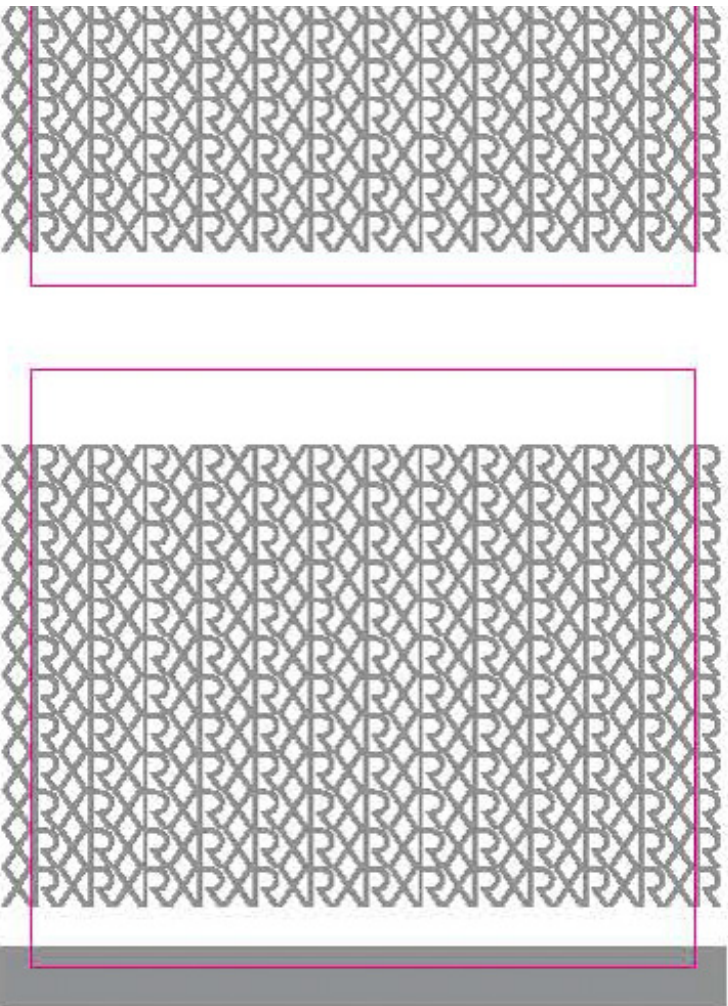
BotaniMedix

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Onychorx
Medicated Nail Pen

2ml | 0.067 FL.oz





DRUG FACTS	
Active Ingredients Undecylenic Acid - 26.5%	Purpose Antifungal
Inactive Ingredients: Alpha Tocopheryl Acetate, Vitamin E, Carnauba Wax, Cetylstearyl Alcohol, Clove Leaf Oil, Dimethyl Sulfoxide, Ethylhexylglycerin, Eucalyptus Oil, Glycerin, Macadamia Nut Oil, Hyaluronic Acid, Isopropyl Palmitate, Peppermint Oil, Phenoxethanol, Polysorbate 80, Propolis Wax, Tea Tree Oil, Urea, Water	
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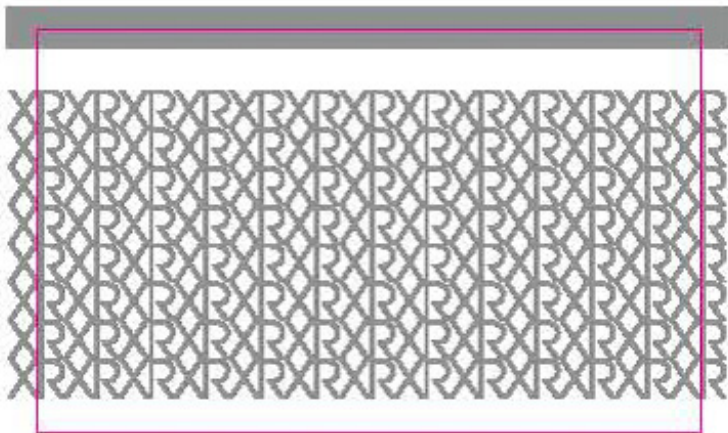


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OnychoRx
Medicated Nail Pen

Our mission at BotaniMedix is to provide high quality medical grade foot care treatments, sold exclusively through Physicians, to deliver safe, effective and natural products that promote well-being and healthy feet.

OnychoRx
The future of nail fungus treatment

This unique, triple action, medicated nail pen eliminates nail fungus by softening the nail allowing our fast acting, maximum strength formula to penetrate and kill fungi at their source.

Questions?
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BotaniMedix



— DR. FORMULATED —
TRIPLE ACTION
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OnychoRx
Medicated Nail Pen

DRUG FACTS

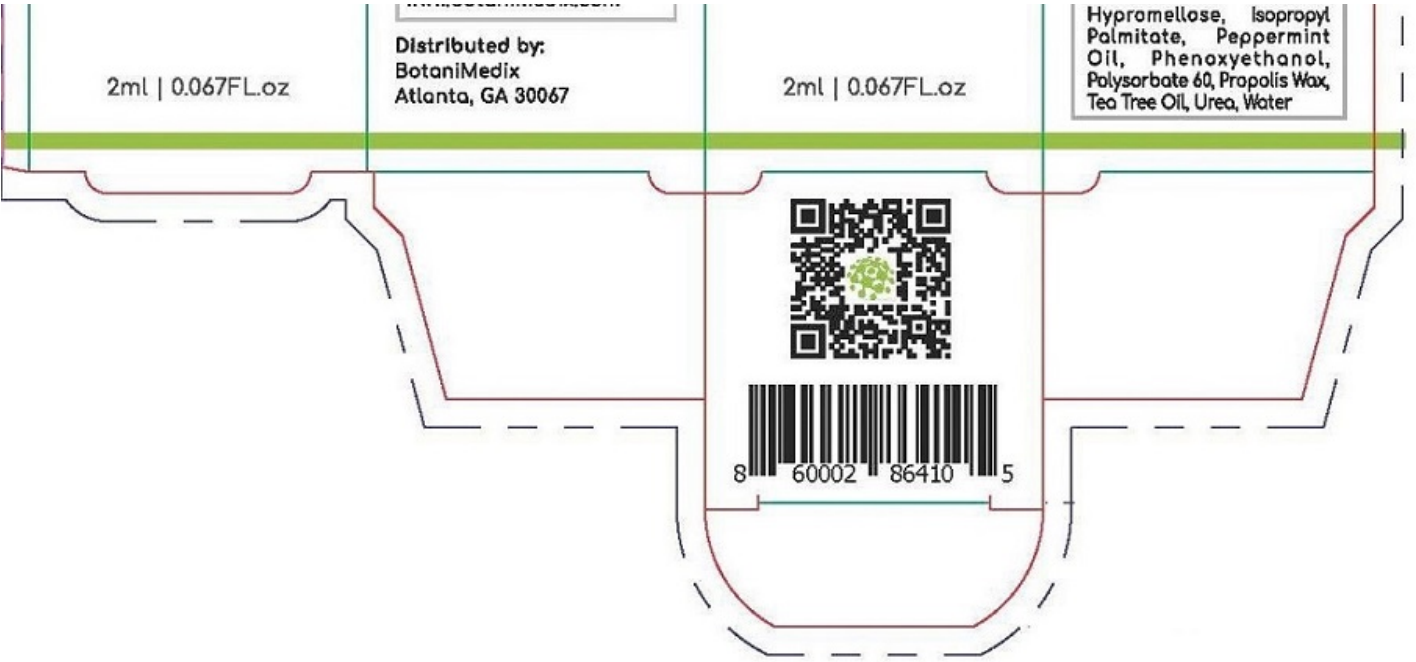
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BOTANIMEDIX ONYCHORX ANTIFUNGAL NAIL GEL

undecylenic acid gel

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:52261-5800
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength
UNDECYLENIC ACID (UNII: K3D86KJ24N) (UNDECYLENIC ACID - UNII:K3D86KJ24N)		UNDECYLENIC ACID	0.2508 kg in 1 kg

Inactive Ingredients	
Ingredient Name	Strength
ISOPROPYL PALMITATE (UNII: 8CRQ2TH63M)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
POLYSORBATE 60 (UNII: CAL22UVI4M)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
UREA (UNII: 8W8T17847W)	
PEPPERMINT OIL (UNII: AV092KU4JH)	
.ALPHA.-TOCOPHEROL ACETATE, DL- (UNII: WR1WPI7EW8)	
PROPOLIS WAX (UNII: 6Y8XYV2NOF)	
HYPROMELLOSE 2208 (15000 MPA.S) (UNII: Z78RG6M2N2)	
WATER (UNII: 059QF0KO0R)	
TEA TREE OIL (UNII: VIF565UC2G)	
EUCALYPTUS OIL (UNII: 2R04ONI662)	
PHENOXYETHANOL (UNII: HIE49ZZ3T)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
CANNABIDIOL (UNII: 19GBJ60SN5)	

CLOVE LEAF OIL (UNII: VCA5491KVF)

DIMETHYL SULFOXIDE (UNII: YOW8V9698H)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:52261-5800-0	1 in 1 CARTON	01/01/2020	
1	NDC:52261-5800-1	0.002 kg in 1 BOTTLE, WITH APPLICATOR; 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	01/01/2020	

Labeler - Cosco International, Inc. (016433141)

Registrant - Cosco International, Inc. (016433141)

Establishment

Name	Address	ID/FEI	Business Operations
Cosco International, Inc.		016433141	manufacture(52261-5800) , label(52261-5800) , pack(52261-5800)

Revised: 1/2020

Cosco International, Inc.