

**FIORE RX ANTIFUNGAL PROPEN- undecylenic acid liquid**

**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.*

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**Drug Facts**

<b>Active Ingredient</b>	<b>Purpose</b>
Undecylenic Acid 3%.....	Anti-fungal

**Anti-fungal**

**Warnings For external use only.**

Do not use on children under 2 years of age unless directed by a doctor.  
KEEP THIS AND ALL MEDICATION OUT OF REACH OF CHILDREN. In case of accidental ingestion, contact a physician, emergency medical care facility or poison control center immediately for advice.

When using this product avoid contact with eyes.

Stop use and ask a doctor if irritation occurs.

**Directions:**

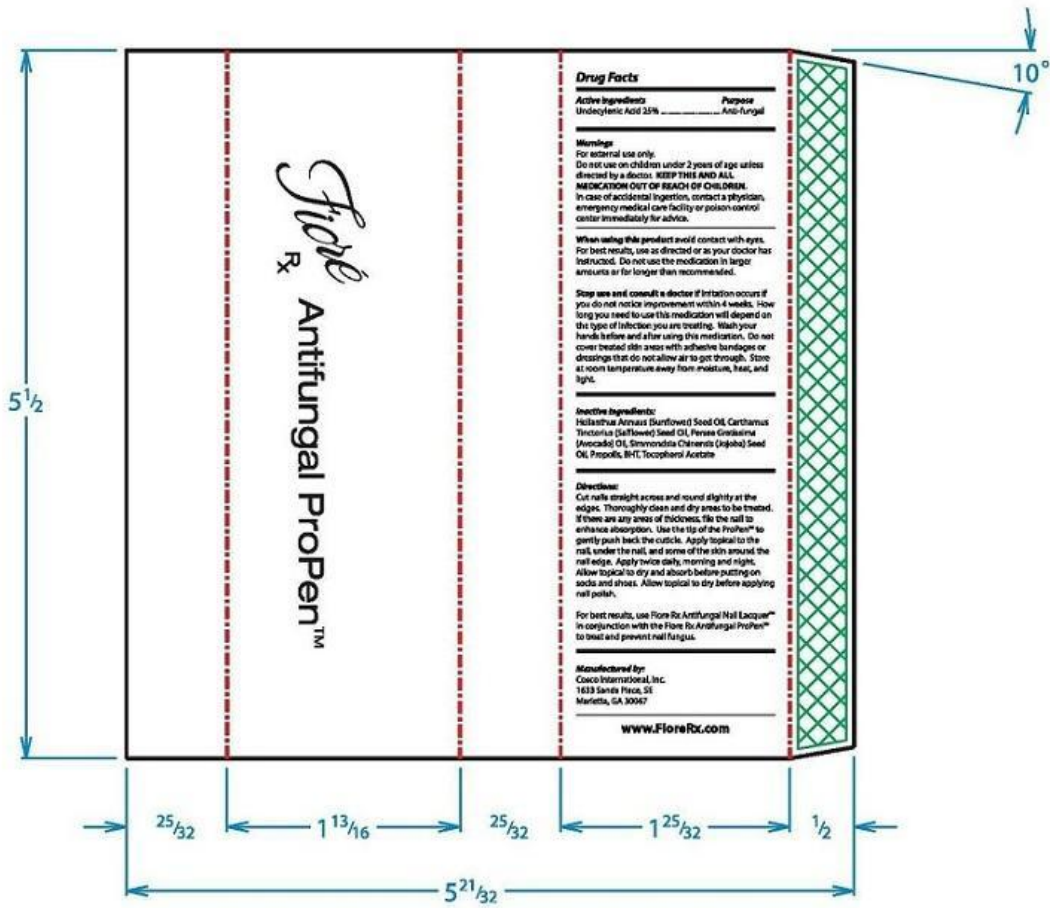
Cut nail straight across and round slightly at the edges. Thoroughly clean and dry areas to be treated. If there are any areas of thickness, file the nail to enhance absorption. Use the tip of the ProPen™ to gently push back the cuticle. Apply topical to the nail, under the nail, and some of the skin around the nail edge. Apply twice daily, morning and night. Allow topical to dry and absorb before putting on socks and shoes. Allow topical to dry before applying nail polish.

For best results, use Fiore Rx Antifungal Nail Lacquer™ in conjunction with the Fiore Rx Antifungal ProPen™ to treat and prevent nail fungus.

**Inactive ingredients:**

Helianthus Annuus (Sunflower) Seed Oil, Carthamus Tinctorius (Safflower) Seed Oil, Persea Gratissima (Avacado) Oil, Simmondsia Chinensis (Jojoba) Seed Oil, Propolis Wax, BHT, Tocopheral Acetate

**Outer Package PLPDP**



Inner Package PLPDP



- Bleed Area
- Print Area

## FIORE RX ANTIFUNGAL PROPEN

undecylenic acid liquid

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:5226 1-2500
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Undecylenic Acid (UNII: K3D86KJ24N) (Undecylenic Acid - UNII:K3D86KJ24N)	Undecylenic Acid	0.5 g in 2 g

### Inactive Ingredients

Ingredient Name	Strength
SUNFLOWER SEED (UNII: R9N3379M4Z)	1.4368 g in 2 g

SAFFLOWER OIL (UNII: 65UEH262IS)	0.03 g in 2 g
AVOCADO OIL (UNII: 6VNO72PFC1)	0.02 g in 2 g
SIMMONDSIA CHINENSIS SEED (UNII: D24K2Q1F6H)	0.01 g in 2 g
PROPOLIS WAX (UNII: 6Y8XYV2NOF)	0.002 g in 2 g
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	0.001 g in 2 g
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	0.0002 g in 2 g

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:52261-2500-1	1 in 1 BOX		
1	NDC:52261-2500-0	2 g in 1 TUBE, WITH APPLICATOR		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333C	05/21/2013	

**Labeler** - Cosco International, Inc. (016433141)

**Registrant** - Cosco International, Inc. (016433141)

### Establishment

Name	Address	ID/FEI	Business Operations
Cosco International, Inc.		016433141	manufacture(52261-2500) , label(52261-2500) , pack(52261-2500)

Revised: 9/2013

Cosco International, Inc.