ANTI-FUNGAL PEN CVS- undecylenic acid liquid CVS

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.

Drug Facts

Active ingredient Purpose

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

Uses

For the cure of most • ringworm (tinea corporis) • athlete's foot (tinea pedis) For the relief of: • itching
• scaling • cracking
• burning • redness • soreness • irritation and discomforts which may accompany these conditions

Warnings
For external use only.
Ask a doctor before use on children under 2 years of age
When using this product avoid contact with eyes
Stop use and ask doctor if • irritation occurs • there is no improvement within 4 weeks

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

Directions

• read all warnings and directions • use only as directed • clean the affected area with soap and water and dry

thoroughly • remove cap from pen • twist the base of the pen, with brush pointing downward, until product dispenses • apply a

thin layer of the product over the affected area twice daily (morning and night) or as directed by a doctor • for athlete's foot: pay

special attention to spaces between the 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 • intended for use by normally

healthy adults only • persons under 18 years of age or those with highly sensitive or allergic skin should use only as directed by a

doctor • supervise children in the use of this product • this product is not effective on the scalp or nails

Inactive ingredients : Isopropyl Palmitate, Propylparaben

Other Information Store at 15°-30°C (59°-86°F) • Keep cap on pen when not in use



Active ingredient Undecylenic Acid 25%	Purpose Anti-funga
Uses For the cure of most • ringworm (tinea corporis) • athlete's foot (tinea pedis) For the relief of: • • burning • redness • soreness • irritation and discomforts which may accompany these condition	
Warnings For external use only.	
Ask a doctor before use on children under 2 years of age	
When using this product avoid contact with eyes	
Stop use and ask doctor if • irritation occurs • there is no improvement within 4 weeks	
Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Cent	er immediately.
Directions • read all warnings and directions • use only as directed • clean the affected ar thoroughly • remove cap from pen • twist the base of the pen, with brush pointing downward, u thin layer of the product over the affected area twice daily (morning and night) or as directed by special attention to spaces between the toes; wear well-fitting, ventilated shoes, and change sh • for athlete's foot and ringworm, use daily for 4 weeks. If condition persists longer, consult a di healthy adults only • persons under 18 years of age or those with highly sensitive or allergic ski doctor • supervise children in the use of this product • this product is not effective on the scalp	until product dispenses • apply a a doctor • for athlete's foot: pay oes and socks at least once daily octor • intended for use by normally in should use only as directed by a
Other Information Store at 15°-30°C (59°-86°F) • Keep cap on pen when not in use	
Inactive ingredients Isopropyl Palmitate, Propylparaben	
This product is not manufactured or distributed by Kramer Laboratories, owner of the re	egistered trademark Fungi-Nail®

ANTI-FUNGAL PEN CVS undecylenic acid liquid **Product Information** HUMAN OTC DRUG NDC:59779-835 Product Type Item Code (Source) **Route of Administration** TOPICAL **Active Ingredient/Active Moiety Ingredient Name** Basis of Strength Strength **Undecylenic Acid** (UNII: K3D86KJ24N) (UNDECYLENIC ACID - UNII:K3D86KJ24N) 25 g in 100 mL Undecylenic Acid **Inactive Ingredients Ingredient Name** Strength ISOPROPYL PALMITATE (UNII: 8CRQ2TH63M) PROPYLPARABEN (UNII: Z8IX2SC10H) Packaging Marketing Start # **Package Description Marketing End Date** Item Code Date 1 NDC:59779-835-01 1 in 1 CARTON 09/15/2016 1.7 mL in 1 CONTAINER; Type 0: Not a Combination 1 Product

Marketing Information						
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date			
OTC monograph final	part333C	09/15/2016				

Labeler - CVS (062312574)

Registrant - Product Quest Mfg (927768135)

Establishment

Name	Address	ID/FEI	Business Operations
Product Quest Mfg		927768135	manufacture(59779-835), label(59779-835)

Revised: 12/2017

CVS