VERRUGUIN- salicylic acid gel Caribe Natural, 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 INGREDIENT:Salicylic Acid 17%

Uses: IFor the removal of common warts. The common wart is easily recognized by the rough "cauliflower-like" appearance of the surface.

□**Keep out of the reach of children.** □ In case of accidental ingestion, get medical help or contact a Poison Control Center immediately.

Verruguin

Removedor de Verrugas

Wart Remover

Salicylic Acid 17%

Directions Adults: ■ Wash affected area and dry thoroughly. Apply small amount at a time with brush to sufficiently cover each wart. Let dry. Repeat this procedure once or twice daily as needed for up to 2 weeks.

WARNING: For external use only. **Do not use;** in or near eyes or mucous membranes, on irritated skin, if prone to allergic reaction to any ingredient in this product, on moles, birthmarks, warts with hair growing from them, genital warts, or warts on the face or mucous membranes, on any area that is infected or reddened, on large areas of the body, on wounds or damaged skin, if you are diabetic, or if you have poor blood circulation. Ask a doctor or pharmacist before use if you are; taking any other medication, or Drinking alcohol. Stop use and ask a doctor if; irritation occurs, condition worsens or does not improve or discomfort persist. If pregnant or breast-feeding. Ask a health professional before use.

Example 1 IKeep the bottle tightly closed

Inactive Ingredients: If lexible collodion, ethyl alcohol.



VERRUGUIN

salicylic acid gel

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:59561-901	
Route of Administration	TOPICAL			

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
SALICYLIC ACID (UNII: O414PZ4LPZ) (SALICYLIC ACID - UNII:O414PZ4LPZ)	SALICYLIC ACID	17 g in 100 g	

Inactive Ingredients		
Ingredient Name	Strength	
PYROXYLIN (UNII: KYR8BR2X6O)		
ETHER (UNII: 0F5N573A2Y)		
ALCOHOL (UNII: 3K9958V90M)		
ISOPROPYL ALCOHOL (UNII: ND2M416302)		

Packaging				
ı	# Item Code	Package Description	Marketing Start Date	Marketing End Date
ı	1 NDC:59561-901-35	15 g in 1 PACKAGE; Type 0: Not a Combination Product		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part358B	05/05/2015	

Labeler - Caribe Natural, Inc (624210480)

Establishment				
Name	Address	ID/FEI	Business Operations	
World Perfumes, Inc		10 13120 44	manufacture (59 56 1-90 1)	

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