

QUITACALLOS- salicylic acid cream
World Perfumes, 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% (w/w)

Corn & Callus Remover

Keep this and all drugs out of the reach of children.

QuitaCallos

Removedor de Callos

Corn & Callus Remover

Salicylic Acid 17%

Directions: Wash affected area and dry thoroughly. Brush on corn or callus only, not on healthy skin. Let dry. Repeat this procedure once or twice daily as needed for up to 14 days (until corn/callus is removed). You may also soak corn/callus in warm water for 5 minutes to assist in removal.

☐**Warnings:** ☐For external use only. Do not use this product on irritated skin, or on any area that is infected or reddened, if you are a diabetic, or if you have poor blood circulation. If discomfort persists, see your doctor or a podiatrist. Extremely flammable. Keep away from fire or flame. Cap bottle tightly and store at room temperature away from heat. If product gets into eye, flush with water for 15 minutes. Avoid inhaling vapors.

☐**Inactive Ingredients:** ☐flexible collodion, isopropyl alcohol.



INDICATIONS: For the removal of corns and calluses. Relieves pain by removing corns and calluses.

DIRECTIONS: Wash affected area and dry thoroughly. Brush on corn or callus only, not on healthy skin. Let dry. Repeat this procedure once or twice daily as needed for up to 14 days (until corn/callus is removed). You may also soak corn/callus in warm water for 5 minutes to assist in removal.

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ACTIVE INGREDIENT: Salicylic Acid 17% (w/w).
INACTIVE INGREDIENTS: Flexible Collodion, Isopropyl Alcohol.

Distributed by:
Germa Products, Inc.
Miami, Florida 33186 / www.germa.net

QUITACALLOS

salicylic acid cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:10095-006
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

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:10095-006-01	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	part358F	05/05/2015	

Labeler - World Perfumes, Inc (101312044)**Establishment**

Name	Address	ID/FEI	Business Operations
World Perfumes, Inc		101312044	manufacture(10095-006)

Revised: 5/2015

World Perfumes, Inc