

ARTICO ICE- menthol 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.

Ingredients - Menthol 1%

USES - Provides temporary relief of minor aches and pains in muscles and joints associated with simple backache, strains, sprains, arthritis and sports injuries.

Keep out of reach of children.

Gel Del Artico

Perfect Purity

Soothing Analgesic Gel

Fast, Temporary Relief from Muscle Aches & Pains

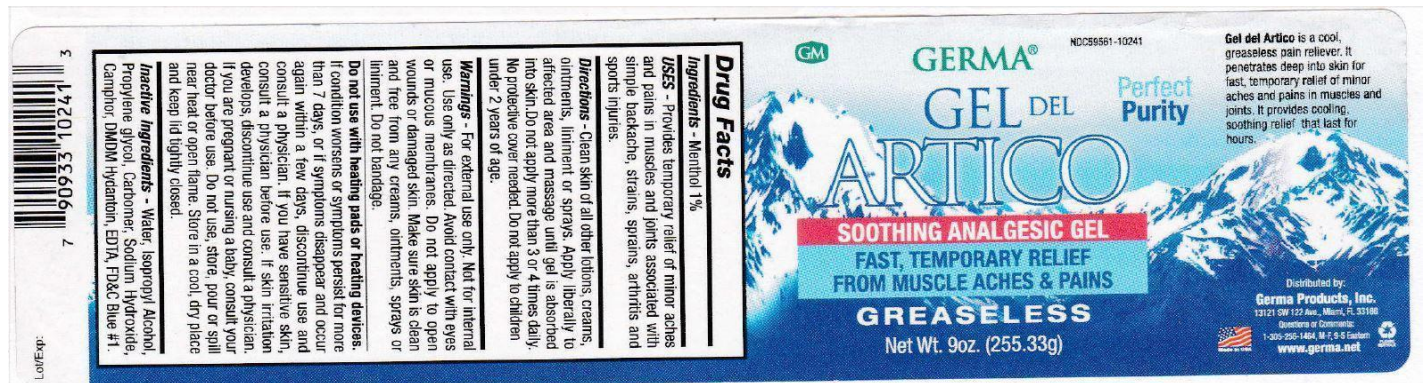
Greaseless

Gel Del Artico is a cool, greaseless pain reliever. It penetrates deep into skin for fast, temporary relief of minor aches and pains in muscles and joints. It provides cooling, soothing relief that last for hours.

Warnings - For external use only. Not for internal use. Use only as directed. Avoid contact with eyes or mucous membranes. Do not apply to open wounds or damaged skin. Make sure skin is clean and free from any creams ointments, sprays or liniment. Do not bandate.

Do not use with heating pads or heating devices. If condition worsens or symptoms persist for more than 7 days, or if symptoms disappear and occur again within a few days, discontinue use and consult a physician. If you have sensitive skin, consult a physician before use. If skin irritation develops, discontinue use and consult a physician. If you are pregnant or nursing a baby, consult your doctor before use. Do not use, store, pour or spill near heat or open flame. Store in a cool, dry place and keep lid tightly closed.

Inactive Ingredients - water, isopropyl alcohol, propylene glycol, carbomer, sodium hydroxide, camphor, dmdm hydantoin, edta, fd&c blue #1



ARTICO ICE			
menthol gel			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:59561-102

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	1 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
CARBOMER COPOLYMER TYPE A (UNII: 71DD5V995L)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
CAMPHOR (NATURAL) (UNII: N20HL7Q941)	
DMDM HYDANTOIN (UNII: BYR0546TOW)	
EDETIC ACID (UNII: 9G34HU7RV0)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59561-102-41	255 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 not final	part348	05/04/2015	

Labeler - Caribe Natural, Inc (624210480)

Establishment

Name	Address	ID/FEI	Business Operations
World Perfumes, Inc		101312044	manufacture(59561-102)

Revised: 4/2015

Caribe Natural, Inc