LEADER ROLL-ON COOLING PAIN RELIEF TOPICAL ANALGESIC- menthol, unspecified form gel Cardinal Health, 110 dba LEADER				
Leader™ Roll-On Cooling Pain Relief Gel Topical Analgesic				
Drug Facts				
Active ingredient				
Menthol 4%				
Purpose				
Topical analgesic				
Uses				
for the temporary relief of minor aches and pains of muscles and joints associated with simple backache, arthritis, strains, and sprains				
Warnings				
For external use only				
Ask a doctor before use if you have sensitive skin				
When using this product				
 Avoid contact with eyes Do not apply to wounds or damaged skin Do not use with other ointments, creams, sprays or liniments Do not apply to irritated skin or if excessive irritation develops Do not bandage tightly Wash hands after use with cool water Do not use with heating pads or heating devices 				
Stop use and consult a doctor if condition worsens, or if symptoms persist for more than 7 days, or clear up and occur again within a few days.				
Flammable				
☐ keep away from excessive heat or open flame				
If pregnant or breast-feeding, ask a health professional before use.				
Keep out of reach of children. If swallowed, get medical help or contact Poison Control Center (1-800-222-1222) immediately.				

Directions

Adults and children 2 years of age and older: Apply to affected area not more
than 3 to 4 times daily
Children under 2 years of age: consult a doctor.

Other information

Store in a cool dry place with lid closed tightly.

Inactive ingredients

aloe barbadensis leaf juice, arnica montana flower extract, blue 1, boswellia serrata resin extract, calendula officinalis flower extract, camellia sinensis leaf extract, camphor, carbomer, glycerin, isopropyl alcohol, isopropyl myristate, silica, sodium hydroxide, tocopheryl acetate, water, yellow 5.

Questions or comments?

1-866-567-8600

DIST. BY CAH DUBLIN, OH 43017

PRINCIPAL DISPLAY PANEL - 74 mL Bottle Label

LEADER™

NDC 70000-0617-1

Roll-On

Cooling

Pain Relief

Gel

Menthol, 4% | Topical Analgesic

Pain Relieving Gel

For Arthritis

Back Pain

Sore Muscles

& Joints

Hands-Free

Roll-On

Applicator

Paraben-Free

COMPARE TO

BIOFREEZE®

100% Money Back Guarantee

2.5 FL OZ (74 mL)



LEADER ROLL-ON COOLING PAIN RELIEF TOPICAL ANALGESIC

menthol, unspecified form gel

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70000-0617	
Route of Administration	TOPICAL			

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A) (MENTHOL, UNSPECIFIED FORM - UNII:L7T10EIP3A)	MENTHOL, UNS PECIFIED FORM	40 mg in 1 mL		

Inactive Ingredients

Ingredient Name	Strength
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
Arnica Montana Flower (UNII: OZ0E5Y15PZ)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
INDIAN FRANKINCENSE (UNII: 4PW41QCO2M)	
Calendula Officinalis Flower (UNII: P0M7O4Y7YD)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
CAMPHOR (SYNTHETIC) (UNII: 5TJD82A1ET)	
CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	
Glycerin (UNII: PDC6A3C0OX)	
Isopropyl Alcohol (UNII: ND2M416302)	
Isopropyl Myristate (UNII: 0RE8K4LNJS)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
Sodium Hydroxide (UNII: 55X04QC32I)	
.ALPHATOCOPHEROL ACETATE, DL- (UNII: WR1WPI7EW8)	
Water (UNII: 059QF0KO0R)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	

Product Characteristics				
Color	GREEN	Score		
Shape		Size		
Flavor		Imprint Code		
Contains				

P	ackaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70000- 0617-1	74 mL in 1 BOTTLE, WTH APPLICATOR; Type 0: Not a Combination Product	11/03/2022	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph drug	M017	11/03/2022	

Labeler - Cardinal Health, 110 dba LEADER (063997360)

Registrant - Garcoa, Inc. (036464697)

Establishment				
Name	Address	ID/FEI	Business Operations	
Sigan Industries INC.		255106239	MANUFACTURE(70000-0617)	