

**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®
active ingredient*

100% Money
Back Guarantee

2.5 FL OZ (74 mL)

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Questions or comments? 1-866-567-8600

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DIST. BY CAH DUBLIN, OH 43017
www.myleader.com 1-800-200-6313
05-4494 Made in Canada

NDC 70000-0617-I

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®
active ingredient*

100% Money
Back Guarantee

2.5 FL OZ (74 mL)

CIN 5804927
REV. 9/22
9629514239

100% Money Back Guarantee

Return to place of purchase if not satisfied.

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, UNSPECIFIED 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: PDC6A3C00X)	
Isopropyl Alcohol (UNII: ND2M416302)	
Isopropyl Myristate (UNII: 0RE8K4LNJS)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
Sodium Hydroxide (UNII: 55X04QC32I)	
.ALPHA.-TOCOPHEROL 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			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70000-0617-1	74 mL in 1 BOTTLE, WITH 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
SV Labs Toronto Corporation		203917476	manufacture(70000-0617)

