

**TOPCARE PAIN RELIEVING ROLL-ON TOPICAL ANALGESIC- menthol,  
unspecified form gel  
Topco Associates LLC**

*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.*

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**TopCare Pain Relieving Roll-On 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 breastfeeding,** ask a health professional before use.

**Keep out of reach of children.** If swallowed, get medical help or contact a 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. Massage not necessary.
- **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?**

**1-888-423-0139**

DISTRIBUTED BY TOPCO ASSOCIATES LLC  
ELK GROVE VILLAGE, IL 60007

### **PRINCIPAL DISPLAY PANEL - 74 mL Bottle Label**

NDC 36800-290-01

TopCare  
health®

COMPARE TO BIOFREEZE® ROLL-ON ACTIVE INGREDIENT\*

Cold Therapy

Pain  
Relieving  
Roll-On Gel

with Menthol 4%

- For Arthritis, Back Pain,  
Sore Muscles & Joints
- No-Mess Applicator
- Vanishing Scent
- Paraben-Free

• OUR PHARMACISTS •  
RECOMMEND

2.5 FL OZ (74 mL)

<b>Drug Facts</b>	
<b>Active ingredient</b> Menthol 4%	<b>Purpose</b> Topical analgesic
<b>Uses</b> For the temporary relief of minor aches and pains of muscles and joints associated with simple backache, arthritis, strains, and sprains	
<b>Warnings</b> 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 breastfeeding, ask a health professional before use. Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center (1-800-222-1222) immediately.	
<b>Directions</b> • Adults and children 2 years of age and older: Apply to affected area not more than 3 to 4 times daily. Massage not necessary. • Children under 2 years of age: Consult a doctor.	
<b>Other information</b> Store in a cool dry place with lid closed tightly	
<b>Inactive ingredients</b> 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.	
<b>Questions or comments?</b> 1-888-423-0139	

\*This product is not manufactured or distributed by Performance Health, owner of the registered trademark Biofreeze®.

DISTRIBUTED BY TOPCO ASSOCIATES LLC  
ELK GROVE VILLAGE, IL 60007  
©TOPCO GLBA0620 QUESTIONS? 1-888-423-0139  
topcare@topco.com www.topcarebrand.com

**✓QUALITY GUARANTEED**

05-3885 MADE IN CANADA

NDC 36800-290-01

COMPARE TO BIOFREEZE® ROLL-ON ACTIVE INGREDIENT\*

## Cold Therapy Pain Relieving Roll-On Gel

with Menthol 4%

- For Arthritis, Back Pain, Sore Muscles & Joints
- No-Mess Applicator
- Vanishing Scent
- Paraben-Free

2.5 FL OZ (74 mL)

## TOPCARE PAIN RELIEVING ROLL-ON TOPICAL ANALGESIC

menthol, unspecified form gel

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:36800-290
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>MENTHOL, UNSPECIFIED FORM</b> (UNII: L7T10EIP3A) (MENTHOL, UNSPECIFIED FORM - UNII:L7T10EIP3A)	MENTHOL, UNSPECIFIED FORM	40 mg in 1 mL

### Inactive Ingredients

Ingredient Name	Strength
<b>ALOE VERA LEAF</b> (UNII: ZY81Z83H0X)	
<b>ARNICA MONTANA FLOWER</b> (UNII: OZ0E5Y15PZ)	
<b>FD&amp;C BLUE NO. 1</b> (UNII: H3R47K3TBD)	
<b>INDIAN FRANKINCENSE</b> (UNII: 4PW41QCO2M)	

<b>CALENDULA OFFICINALIS FLOWER</b> (UNII: P0M7O4Y7YD)
<b>GREEN TEA LEAF</b> (UNII: W2ZU1RY8B0)
<b>CAMPHOR (SYNTHETIC)</b> (UNII: 5TJD82A1ET)
<b>CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE</b> (UNII: 0A5MM307FC)
<b>Glycerin</b> (UNII: PDC6A3C0OX)
<b>Isopropyl Alcohol</b> (UNII: ND2M416302)
<b>Isopropyl Myristate</b> (UNII: 0RE8K4LNJS)
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)
<b>Sodium Hydroxide</b> (UNII: 55X04QC32I)
<b>.ALPHA.-TOCOPHEROL ACETATE, DL-</b> (UNII: WR1WPI7EW8)
<b>Water</b> (UNII: 059QF0KO0R)
<b>FD&amp;C YELLOW NO. 5</b> (UNII: I753WB2F1M)

**Product Characteristics**

<b>Color</b>	WHITE	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>		<b>Imprint Code</b>	
<b>Contains</b>			

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:36800-290-01	74 mL in 1 BOTTLE, WITH APPLICATOR; Type 0: Not a Combination Product	09/03/2020	

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part348	09/03/2020	

**Labeler - Topco Associates LLC (006935977)**

**Registrant - Garcoa, Inc. (036464697)**

**Establishment**

Name	Address	ID/FEI	Business Operations
Sigan Industries INC.		255106239	MANUFACTURE(36800-290)