

**BIOFREEZE ROLL-ON- menthol gel**  
**RB Health (US) LLC**

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**Biofreeze<sup>®</sup> Roll-On**

***Drug Facts***

**Active ingredient**

Menthol 4%

**Purpose**

Pain Relieving Gel

**Uses**

Temporarily relieves minor aches and pains of muscles and joints associated with:

- simple backache
- arthritis
- strains
- bruises
- sprains

**Warnings**

**For external use only.**

**Flammable: Keep away from excessive heat or open flame**

**When using this product**

- use only as directed
- avoid contact with the eyes or on mucous membranes
- do not apply to wounds or damaged skin
- do not apply to irritated skin or if excessive irritation develops
- do not bandage tightly or use with heating pad or device

**Stop use and ask a doctor if**

- you experience pain, swelling or blistering of the skin
- condition worsens, or if symptoms persist for more than 7 days or clear up and occur again within a few days
- arthritic pain persists for more than 10 days, or redness is present, or in conditions affecting children under 12 years of age

**If pregnant or breast-feeding,**ask a health professional before use.

**Keep out of reach of children.**If swallowed, get medical help or contact a Poison Control Center right away.

## **Directions**

- adults and children 2 years of age and older: rub a thin film over affected area not more than 3 to 4 times daily
- children under 2 years of age: consult a physician
- wash hands after use with cool water

## **Other information**

- store at 20-25°C (68-77°F)
- store in a cool dry place away from direct sunlight

## **Inactive ingredients**

Aloe Barbadensis Leaf Extract, Arctium Lappa Root (Burdock) Extract, Arnica Montana Flower Extract, Blue 1, Boswellia Carterii Resin Extract, Calendula Officinalis Extract, Camellia Sinensis Leaf Extract, Camphor, Carbomer, Glycerin, Ilex Paraguariensis Leaf Extract, Isopropyl Alcohol, Isopropyl Myristate, Melissa Officinalis (Lemon Balm) Leaf Extract, Silica, Tocopheryl Acetate, Triethanolamine, Water, Yellow 5

## **Questions or comments?**

**1-800-246-3733**

Dist. by: RB Health (US), Parsippany, NJ 07054-0224

## **PRINCIPAL DISPLAY PANEL - 89 mL Bottle Carton**

CLINICALLY  
RECOMMENDED\*

NDC 59316-205-10

BiOFREEZE<sup>®</sup>  
COOL THE PAIN

ROLL-ON  
MENTHOL-PAIN  
RELIEVING GEL

3 FL OZ (89 mL)

SHAKE WELL  
BEFORE EACH USE

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## Drug Facts (continued)

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\*Based on a survey of Clinicians: chiropractors, podiatrists, massage therapists, physical therapists, retail pharmacists, and athletic trainers (IPSOS Clinician Survey).

Does not contain NSAIDs, Ibuprofen, Aspirin or Salicylate • No Animal Testing 11806 P05132-R09



## BIOFREEZE ROLL-ON

menthol gel

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:59316-205
<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>ARNICA MONTANA FLOWER</b> (UNII: OZ0E5Y15PZ)	
<b>FRANKINCENSE</b> (UNII: R9XLF1R1VM)	
<b>CALENDULA OFFICINALIS FLOWER</b> (UNII: P0M7O4Y7YD)	
<b>ALOE VERA LEAF</b> (UNII: ZY81Z83H0X)	
<b>GREEN TEA LEAF</b> (UNII: W2ZU1RY8B0)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>ILEX PARAGUARIENSIS LEAF</b> (UNII: 1Q953B404F)	
<b>ISOPROPYL ALCOHOL</b> (UNII: ND2M416302)	
<b>ISOPROPYL MYRISTATE</b> (UNII: 0RE8K4LNJS)	
<b>MELISSA OFFICINALIS LEAF</b> (UNII: 50D2ZE9219)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>.ALPHA.-TOCOPHEROL ACETATE</b> (UNII: 9E8X80D2L0)	
<b>TROLAMINE</b> (UNII: 9O3K93S3TK)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>FD&amp;C BLUE NO. 1</b> (UNII: H3R47K3TBD)	
<b>FD&amp;C YELLOW NO. 5</b> (UNII: I753WB2F1M)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59316-205-10	89 mL in 1 BOTTLE; Type 0: Not a Combination Product	01/17/2013	
2	NDC:59316-205-14	74 mL in 1 BOTTLE; Type 0: Not a Combination Product	01/17/2013	

3	NDC:59316-205-81	2 in 1 CARTON	02/22/2022	
3	NDC:59316-205-10	89 mL in 1 BOTTLE; Type 0: Not a Combination Product		
4	NDC:59316-205-09	37 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/15/2024	
5	NDC:59316-205-82	2 in 1 CARTON	03/25/2024	
5	NDC:59316-205-10	89 mL in 1 BOTTLE; Type 0: Not a Combination Product		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M017	01/17/2013	

**Labeler** - RB Health (US) LLC (081049410)

Revised: 3/2024

RB Health (US) LLC