

**BIOFREEZE- menthol spray**  
**RB Health (US) LLC**

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**Biofreeze**

***Drug Facts***

**Active ingredient**

Menthol 10.5%

**Purpose**

Pain Relieving Spray

**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**

**Contents under pressure. Do not puncture or incinerate.**

**Do not store at temperature above 120°F.**

**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

**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 12 years of age and older: spray on to affected area not more than 3 to 4 times daily; massage not necessary
- children under 12 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**

Alcohol Denat., Arnica Montana Flower Extract, Calendula Officinalis Flower Extract, Camellia Sinensis Leaf Extract, Chamomilla Recutita (Matricaria) Flower Extract, Dimethyl Sulfone (MSM), Echinacea Angustifolia Extract, Ilex Paraguariensis Leaf Extract, Isopropyl Myristate, Juniperus Communis Fruit Extract, Water

### **Questions or comments?**

**1-800-246-3733**

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

### **PRINCIPAL DISPLAY PANEL - 118 mL Bottle Label**

CLINICALLY  
RECOMMENDED\*

NDC 59316-114-25

BiOFREEZE®  
COOL THE PAIN

SPRAY

MENTHOL-PAIN  
RELIEVING SPRAY

4 FL OZ (118 mL)

360°  
SPRAY

PRESS DOWN FIRMLY TO  
ACTIVATE SPRAYER FOR FIRST USE



NDC 59316-114-25

# BIOFREEZE<sup>®</sup>

## COOL THE PAIN

### SPRAY

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

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

No Animal Testing • Does not contain NSAIDs, Ibuprofen, Aspirin or Salicylate

www.biofreeze.com  
DOT SP 15792 M5655  
12149 P05664-R08



## BIOFREEZE

menthol spray

### Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:59316-114

Route of Administration

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	105 mg in 1 mL	
Inactive Ingredients				
Ingredient Name			Strength	
<b>ALCOHOL</b> (UNII: 3K9958V90M)				
<b>ARNICA MONTANA FLOWER</b> (UNII: OZ0E5Y15PZ)				
<b>CALENDULA OFFICINALIS FLOWER</b> (UNII: P0M7O4Y7YD)				
<b>GREEN TEA LEAF</b> (UNII: W2ZU1RY8B0)				
<b>CHAMOMILE</b> (UNII: FGL3685T2X)				
<b>DIMETHYL SULFONE</b> (UNII: 9H4PO4Z4FT)				
<b>ECHINACEA ANGUSTIFOLIA WHOLE</b> (UNII: VB06AV5US8)				
<b>ILEX PARAGUARIENSIS LEAF</b> (UNII: 1Q953B4O4F)				
<b>ISOPROPYL MYRISTATE</b> (UNII: 0RE8K4LNJS)				
<b>JUNIPER BERRY</b> (UNII: O84B5194RL)				
<b>WATER</b> (UNII: 059QF0KO0R)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59316-114-50	10 in 1 BOX	02/19/2014	12/31/2021
1		1 mL in 1 PACKET; Type 0: Not a Combination Product		
2	NDC:59316-114-25	118 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	02/19/2014	
3	NDC:59316-114-30	473 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	02/19/2014	
4	NDC:59316-114-10	89 mL in 1 BOTTLE; Type 0: Not a Combination Product	09/19/2016	
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC Monograph Drug	M017	02/19/2014		

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