

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

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**Biofreeze Spray**

***Drug Facts***

***Active Ingredients:***

Menthol 10.5%

***Purpose:***

Cooling Pain Relief

**Uses**

Temporary relief from minor aches and pains of sore muscles and joints associated with: arthritis backache strains and 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**

**Ask a Doctor Before using If You have:**

- 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

**When Using This Product**

Avoid contact with the eyes or mucous membranes; 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; Wash hands after use with cool water; Do not use with heating pad or device; Store in a cool dry place

**Stop Use And Ask A Doctor If:**

Condition worsens, or if symptoms persist for more than 7 days, or clear up and recur

**If pregnant or breast-feeding:**

Ask a health professional before use

**Keep out of reach of children:**

If accidentally ingested, get medical help or contact a Poison Control Center immediately

***Directions:***

**Adults and children 12 years of age and older:**Spray on to the affected areas not more than 4 times daily; massage not necessary

**Children under 12 years of age:**Consult physician

***Inactive Ingredients***

Alcohol, Arnica Montana Flower Extract, Calendula Officinalis Flower Oil, Camellia Sinensis Leaf Oil, Chamomilla Recutita (Matricaria) Flower Extract, Denatonium Benzoate, Echinacea Angustifolia Extract, Glycerin, Ilex Paraguariensis Leaf Extract, Isopropyl Alcohol, Isopropyl Myristate, Juniperus Communis Fruit Extract, Methylsulfonylmethane, Purified Water, Tert-Butyl Alcohol

***Questions or Comments:***

**1-800-246-3733**

**Package Labeling:**



NDC 59316-833-10

# BIOFREEZE<sup>®</sup>

COOL THE PAIN

SPRAY

MENTHOL - PAIN  
RELIEVING SPRAY

3 FL OZ (89 mL)



PRESS DOWN FIRMLY TO  
ACTIVATE SPRAYER FOR FIRST USE



XXXXXXXXXXXX

### Drug Facts

**Active ingredient**                      **Purpose**  
Menthol 10.5%.....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

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

### Drug Facts (continued)

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, Arnica Montana Flower Extract, Calendula Officinalis Flower Oil, Camellia Sinensis Leaf Oil, Chamomilla Recutita (Matricaria) Flower Extract, Denatonium Benzoate, Echinacea Angustifolia Extract, Glycerin, Ilex Paraguariensis Leaf Extract, Isopropyl Alcohol, Isopropyl Myristate, Juniperus Communis Fruit Extract, Methylsulfonylmethane, Purified Water, Tert-Butyl Alcohol

**Questions or comments? 1-866-682-4639**

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

**www.biofreeze.com**  
DOT 2P M5793

121523 3292804  
No Animal Testing  
Does not contain NSAIDs,  
Ibuprofen, Aspirin or Salicylate



## BIOFREEZE

menthol spray

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:59316-833
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	105 mg in 1 mL

### Inactive Ingredients

XXXXXXXXXXXX

Ingredient Name	Strength
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
DENATONIUM BENZOATE (UNII: 4YK5Z54AT2)	
TERT-BUTYL ALCOHOL (UNII: MD83SFE959)	
ARNICA MONTANA FLOWER (UNII: OZ0E5Y15PZ)	
CALENDULA OFFICINALIS FLOWER (UNII: P0M7O4Y7YD)	
CHAMOMILE (UNII: FGL3685T2X)	
DIMETHYL SULFONE (UNII: 9H4PO4Z4FT)	
ALCOHOL (UNII: 3K9958V90M)	
ILEX PARAGUARIENSIS LEAF (UNII: 1Q953B404F)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
JUNIPER BERRY (UNII: O84B5194RL)	
WATER (UNII: 059QF0KO0R)	
ECHINACEA ANGUSTIFOLIA WHOLE (UNII: VB06AV5US8)	
TEA LEAF OIL (UNII: VC855RRT77)	
GLYCERIN (UNII: PDC6A3C0OX)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59316-833-10	89 mL in 1 BOTTLE; Type 0: Not a Combination Product	12/01/2023	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M017	12/01/2023	

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

Revised: 2/2024

RB Health (US) LLC