

**BIOFREEZE COLORLESS- menthol gel**  
**RB Health (US) LLC**

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**Biofreeze® Colorless**

***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 Barbadosis Leaf Extract, Arctium Lappa Root (Burdock) Extract, Arnica Montana Flower Extract, 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

## **Questions or comments?**

**1-800-246-3733**

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

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

CLINICALLY  
RECOMMENDED\*

BiOFREEZE<sup>®</sup>  
COOL THE PAIN

NDC 59316-103-12

COLORLESS GEL

MENTHOL-PAIN  
RELIEVING GEL

3 FL OZ (89 mL)



**Active Ingredient/Active Moiety**

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

**Inactive Ingredients**

<b>Ingredient Name</b>	<b>Strength</b>
<b>ALOE VERA LEAF</b> (UNII: ZY81Z83H0X)	
<b>ARCTIUM LAPPAL ROOT</b> (UNII: 597E9BI3Z3)	
<b>ARNICA MONTANA FLOWER</b> (UNII: OZ0E5Y15PZ)	
<b>FRANKINCENSE</b> (UNII: R9XLF1R1WM)	
<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>ILEX PARAGUARIENSIS LEAF</b> (UNII: 1Q953B4O4F)	
<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)	

**Packaging**

<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:59316-103-40	946 mL in 1 BOTTLE; Type 0: Not a Combination Product	01/03/2012	
2	NDC:59316-103-10	5 mL in 1 BOTTLE; Type 0: Not a Combination Product	01/03/2012	12/31/2014
3	NDC:59316-103-11	3 mL in 1 BOTTLE; Type 0: Not a Combination Product	01/03/2012	12/31/2021
4	NDC:59316-103-15	89 mL in 1 BOTTLE, WITH APPLICATOR; Type 0: Not a Combination Product	01/03/2012	12/31/2018
5	NDC:59316-103-20	118 mL in 1 BOTTLE; Type 0: Not a Combination Product	01/03/2012	
6	NDC:59316-103-12	89 mL in 1 BOTTLE; Type 0: Not a Combination Product	09/19/2016	
7	NDC:59316-103-28	273 mL in 1 BOTTLE; Type 0: Not a Combination Product	09/19/2016	12/31/2019

**Marketing Information**

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
OTC Monograph Drug	M017	01/03/2012	

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

Revised: 12/2024

RB Health (US) LLC