

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

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**Biofreeze Cream**

***Drug Facts***

***Active Ingredients:***

Menthol USP 10%

***Purpose***

Cooling Pain Relief

***Uses:***

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

***Warnings:***

**For external use only**

**Ask a doctor before use if you have:**

Sensitive skin

**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 breastfeeding:**

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:** Rub a thin film over affected areas not more four times daily; massage not necessary
- **Children under 12 years of age:** Consult physician

## Inactive Ingredients:

Caprylic/Capric Triglyceride, Caprylyl Glycol, Alcohol, Dimethicone, Gluconolactone Glycerin, Glyceryl Stearate, Hydroxyacetophenone, Ilex Paraguariensis Leaf Extract, Iodopropynyl Butylcarbamate, Phenoxyethanol, Polysorbate 60, Sodium Benzoate, Sodium Hydroxide, Sodium Stearoyl Lactylate, Tocopheryl Acetate, Vitis Vinifera (Grape) Seed Oil, Water, Calcium Gluconate, Cetostearyl Alcohol, Edetate Sodium, Isopropyl Alcohol, PEG-4 Laurate

## Questions or Comments:

1-800-246-3733

## Package Labeling:

**Drug Facts**  
**Active Ingredient** Menthol 10% **Purpose** Pain Relieving Cream  
**Uses** Temporarily relieves minor aches and pains of muscles and joints associated with: ■ simple backache ■ arthritis ■ strains ■ bruises ■ sprains  
**Warnings**  
 For external use only.  
 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 lightly 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.  
 No Animal Testing  
 Does not contain NSAIDs, Ibuprofen, Aspirin or Salicylate  
 www.biofreeze.com  
 012224 - 3261155  
 Knockout Area Does not print

**Drug Facts (continued)**  
**Directions**  
 ■ adults and children 12 years of age and older: rub a thin film over affected area not more than 3 to 4 times daily  
 ■ 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, Calcium Gluconate, Caprylic/Capric Triglyceride, Caprylyl Glycol, Dimethyl Acetol Dimethicone, Edetate Sodium, Gluconolactone, Glycerin, Glyceryl Stearate, Hydroxyacetophenone, Ilex Paraguariensis Leaf Extract, Iodopropynyl Butylcarbamate, Isopropyl Alcohol, PEG-4 Laurate, Phenoxyethanol, Polysorbate 60, Purified Water, Sodium Benzoate, Sodium Hydroxide, Sodium Stearoyl Lactylate, Tocopheryl Acetate  
**Questions or comments?** 1-800-246-3733  
 Dist. by: RB Health (US), Parsippany, NJ 07054-0224 ©2023 RB Health

**BIOFREEZE**  
 COOL THE PAIN  
 CREAM  
 NDC 59316-869-10  
**BIOFREEZE**  
 COOL THE PAIN  
 CREAM  
 MENTHOL-PAIN RELIEVING CREAM  
 Net wt 3 OZ (85 g)

## BIOFREEZE

menthol cream

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:59316-869
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A) (MENTHOL, UNSPECIFIED FORM - UNII:L7T10EIP3A)</b>	MENTHOL, UNSPECIFIED FORM	100 mg in 1 g

## Inactive Ingredients

Ingredient Name	Strength
<b>ALCOHOL</b> (UNII: 3K9958V90M)	
<b>CETOSTEARYL ALCOHOL</b> (UNII: 2DMT128M1S)	
<b>ISOPROPYL ALCOHOL</b> (UNII: ND2M416302)	
<b>PEG-4 LAURATE</b> (UNII: AYF4VM3N1Z)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>CALCIUM GLUCONATE</b> (UNII: SQE6VB453K)	
<b>MEDIUM-CHAIN TRIGLYCERIDES</b> (UNII: C9H2L21V7U)	
<b>CAPRYLYL GLYCOL</b> (UNII: 00YIU5438U)	
<b>DIMETHICONE</b> (UNII: 92RU3N3Y1O)	
<b>GLUCONOLACTONE</b> (UNII: WQ29KQ9POT)	
<b>GLYCERYL MONOSTEARATE</b> (UNII: 230OU9XXE4)	
<b>HYDROXYACETOPHENONE</b> (UNII: G1L3HT4CMH)	
<b>ILEX PARAGUARIENSIS LEAF</b> (UNII: 1Q953B4O4F)	
<b>IODOPROPYNYL BUTYLCARBAMATE</b> (UNII: 603P14DHEB)	
<b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)	
<b>POLYSORBATE 60</b> (UNII: CAL22UVI4M)	
<b>SODIUM BENZOATE</b> (UNII: OJ245FE5EU)	
<b>SODIUM HYDROXIDE</b> (UNII: 55X04QC32I)	
<b>SODIUM STEAROYL LACTYLATE</b> (UNII: IN99IT31LN)	
<b>EDETATE SODIUM</b> (UNII: MP1J8420LU)	
<b>.ALPHA.-TOCOPHEROL ACETATE</b> (UNII: 9E8X80D2L0)	
<b>GRAPE SEED OIL</b> (UNII: 930MLC8XGG)	
<b>WATER</b> (UNII: 059QF0KOOR)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59316-869-10	85 g in 1 JAR; Type 0: Not a Combination Product	03/21/2020	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M017	03/21/2020	

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