

**BIOFREEZE PAIN RELIEF- menthol, unspecified form cream  
RB Health (US) LLC**

*Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.*

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**Biofreeze Pain Relief Cream**

**Drug Facts**

***Active Ingredients***

Menthol 10%

***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.**

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

Sensitive skin

**When using this product:**

- Avoid contact with 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:** Rub a thin film over affected areas not more than 4 times daily; massage not necessary.
- **Children under 12 years of age:** Consult physician

**Inactive Ingredients**

Caprylic/Capric Triglyceride, Cetearyl Alcohol, Diazolidinyl Urea, Dimethicone, Gluconolactone, Glycerin, Glyceryl Stearate, Ilex Paraguariensis Leaf Extract, Iodopropynyl butylcarbamate, Polysorbate 60, Sodium Benzoate, Sodium Hydroxide, Sodium Stearoyl Lactylate, Tetrasodium EDTA, Tocopheryl Acetate, Vitis Vinifera (Grape) seed Oil, Water

**Questions or Comments**

1-800-246-3733

**Package Labeling:**



**NON-GREASY  
PARABEN-FREE**

Does not contain NSAIDs, Ibuprofen, Aspirin or Salicylate

Manufactured in the USA    No Animal Testing

\*Trusted by pharmacists, physical therapists, chiropractors, massage therapists and podiatrists

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**Drug Facts** (continued)

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**For best results, use Biofreeze® in combination with care from a health professional. Find one in your area at Biofreeze.com**

P09842 REV 3

NDC 59316-307-10  
P09855 REV 2

7 31124 00100 9

**CLINICALLY RECOMMENDED #1**

**BIOFREEZE**  
COOL THE PAIN

COLD THERAPY PAIN RELIEF FOR SORE MUSCLES, BACKACHES, SORE JOINTS AND ARTHRITIS

LONG-LASTING • DEEP PENETRATING • NATURAL MOISTURIZERS  
NON-GREASY • PARABEN-FREE

IF ANY LABEL INFORMATION IS MISSING CONTACT PERFORMANCE HEALTH BEFORE USING  
©2018 Performance Health, LLC 1245 Home Avenue, Akron, OH 44310 [biofreeze.com](http://biofreeze.com) 1-800-246-3733

<b>BIOFREEZE PAIN RELIEF</b>			
menthol, unspecified form cream			
<b>Product Information</b>			
<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:59316-307
<b>Route of Administration</b>	TOPICAL		
<b>Active Ingredient/Active Moiety</b>			
	<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	100 mg in 1 mL

## Inactive Ingredients

Ingredient Name	Strength
<b>TRICAPRIN</b> (UNII: O1PB8EU98M)	
<b>CETOSTEARYL ALCOHOL</b> (UNII: 2DMT128M1S)	
<b>DIAZOLIDINYL UREA</b> (UNII: H5RIZ3MPW4)	
<b>DIMETHICONE</b> (UNII: 92RU3N3Y1O)	
<b>GLUCONOLACTONE</b> (UNII: WQ29KQ9POT)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>GLYCERYL MONOSTEARATE</b> (UNII: 230OU9XXE4)	
<b>ILEX PARAGUARIENSIS LEAF</b> (UNII: 1Q953B4O4F)	
<b>IODOPROPYNYL BUTYLCARBAMATE</b> (UNII: 603P14DHEB)	
<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:59316-307-10	1 in 1 CARTON	03/07/2018	12/31/2024
1		89 mL in 1 JAR; Type 0: Not a Combination Product		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	03/07/2018	12/31/2024

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

Revised: 12/2021

RB Health (US) LLC