

**BIOFREEZE FOOT PAIN RELIEF SET- menthol**  
**RB Health (US) LLC**

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**Biofreeze Foot Pain Relief Set**

***Drug Facts***

***Active ingredient:***

Menthol 10%

***Purpose***

Pain Relieving Cream

***Uses:***

Temporarily relieves minor aches and pains of muscles and joints associated with: • arthritis • simple backache • strains • sprains • bruises

***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 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 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 right away

***Directions:***

- Adults and Children 12 years of age and older: Rub a thin film over affected areas not

more than 3 to 4 times daily;

- Children under 12 years of age: Consult a physician
- wash hands after use with cool water

**Inactive ingredients:**

Caprylic/Capric Triglyceride, Caprylyl Glycol, Cetearyl Alcohol, Dimethicone, Gluconolactone, Glycerin, Glyceryl Stearate, Hydroxyacetophenone, Ilex Paraguariensis Leaf Extract, Iodopropynyl Butylcarbamate, Phenoxyethanol, 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

**PRINCIPAL DISPLAY PANEL - 85 g Tube Kit**

NDC 59316-002-10

BiOFREEZE<sup>®</sup>  
COOL THE PAIN

FOOT PAIN  
RELIEF SET

MENTHOL-PAIN  
RELIEVING CREAM

FOOT ROLLER intended to  
relieve foot pain and pain associated  
with plantar fasciitis

1 Biofreeze Foot Cream Tube  
Net wt 3 OZ (85 g)  
+ 1 Foot Roller



# BIOFREEZE

COOL THE PAIN

1 FOOT CREAM | 1 FOOT ROLLER

NDC 59316-002-10

## BIOFREEZE

COOL THE PAIN

### ROLLER INSTRUCTIONS



#### TOE STRETCH

1. While in a seated position, place the Foot Roller on the ground.
2. Place your big toe on the Foot Roller and the rest of your foot on the ground.
3. Apply pressure with your toe to the Foot Roller to stretch the bottom of your foot.
4. Try lifting your heel while keeping the toe on the Foot Roller to improve the stretch.
5. Perform the stretching exercises 2 to 3 times a day, holding the stretch for 15-30 seconds each.



#### ROLLER MASSAGE

1. While in a seated position, place the Foot Roller on the ground and your bare foot on top.
2. Apply pressure with your foot to the Foot Roller and slowly roll the Foot Roller in a back and forth motion from the ball of your foot to the heel.
3. Repeat for 3 to 5 minutes.



## FOOT PAIN RELIEF SET

MENTHOL-PAIN RELIEVING CREAM

**FOOT ROLLER** intended to relieve foot pain and pain associated with plantar fasciitis

**1 Biofreeze Foot Cream Tube**  
Net wt 3 OZ (85 g)  
**+ 1 Foot Roller**

# BIOFREEZE

COOL THE PAIN

\*Based on a survey of Clinicians: chiropractors, podiatrists, massage therapists,

physical therapists, retail pharmacists, and athletic trainers (IPSOS Clinician Survey).



No Animal Testing  
Does not contain NSAIDs,  
Ibuprofen, Aspirin or Salicylate  
[www.biofreeze.com](http://www.biofreeze.com)  
15029 P11132-R04

**BIOFREEZE**  
COOL THE PAIN

## FOOT PAIN RELIEF SET

### IMPORTANT SAFETY INFORMATION

Before each use of the Foot Roller, follow these instructions: Consult your physician before starting any exercise program. Children and persons with medical conditions should not use this product unless first approved by a physician. This product contains Dry Natural Rubber; some persons may be allergic. Stop use if you notice a reaction. Rolling Massage stretch is a guideline and does not replace instructions or directions provided by a doctor or therapist. Inspect product for damage before each use. Discard and replace the product if damaged. This product is not a toy. Keep out of reach of children and pets.

When using the Foot Roller, always follow these instructions: If you have dizziness, trouble breathing, increasing pain, or begin to feel sick with the exercises, stop use and consult your healthcare provider immediately. Children should only use if prescribed by a doctor, and only with adult supervision. This product is recommended for individual use only.

**Caring for the Foot Roller:**  
Inspect after each use. To Clean: Use a mild soap and warm water, then pat dry. Store in a cool, dry place, out of direct sunlight and extreme temperatures.

Before each use of Biofreeze Foot Cream: Refer to product label and read carefully before use.

**BIOFREEZE**  
COOL THE PAIN

### Drug Facts

**Active ingredient** Purpose  
Menthol 10%.....Pain Relieving Cream

**Uses**  
Temporarily relieves minor aches and pains of muscles and joints associated with:  
■ 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 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.

### Drug Facts (continued)

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: 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**  
Caprylic/Capric Triglyceride, Caprylyl Glycol, Cetearyl Alcohol, Dimethicone, Gluconolactone, Glycerin, Glyceryl Stearate, Hydroxyacetophenone, Ilex Paraguariensis Leaf Extract, Iodopropynyl Butylcarbamate, Phenoxethanol, Polysorbate 80, Sodium Benzoate, Sodium Hydroxide, Sodium Stearoyl Lactylate, Tetrasodium EDTA, Tocopheryl Acetate, Vitis Vinifera (Grape) Seed Oil, Water

**Questions or comments?**  
1-800-246-3733

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**COLD THERAPY PAIN RELIEF FOR SORE MUSCLES, JOINTS, SIMPLE BACKACHES, ARTHRITIS, STRAINS, BRUISES AND SPRAINS.**



1 FOOT



1 FOOT



## BIOFREEZE FOOT PAIN RELIEF SET

menthol kit

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:59316-002
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### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59316-002-10	1 in 1 KIT	03/12/2021	

### Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	1 TUBE	85 g

## Part 1 of 1

### BIOFREEZE FOOT CREAM

menthol cream

### Product Information

<b>Item Code (Source)</b>	NDC:59316-001
<b>Route of Administration</b>	TOPICAL

### Active Ingredient/Active Moiety

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

### Inactive Ingredients

Ingredient Name	Strength
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<b>MEDIUM-CHAIN TRIGLYCERIDES</b> (UNII: C9H2L21V7U)
<b>CAPRYLYL GLYCOL</b> (UNII: 00YIU5438U)
<b>CETOSTEARYL ALCOHOL</b> (UNII: 2DMT128M1S)
<b>DIMETHICONE</b> (UNII: 92RU3N3Y1O)
<b>GLUCONOLACTONE</b> (UNII: WQ29KQ9POT)
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)
<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: 059QF0KO0R)

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59316-001-10	85 g in 1 TUBE; Type 0: Not a Combination Product		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M017	03/12/2021	

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OTC Monograph Drug	M017	03/12/2021	

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