

**BIOFREEZE FOOT PAIN RELIEF SET- menthol
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.

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®

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

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Net wt 3 OZ (85 g)
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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
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

Product Type	HUMAN OTC DRUG	Item Code (Source)	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

Item Code (Source)	NDC:59316-001
Route of Administration	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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MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)
CAPRYLYL GLYCOL (UNII: 00YIU5438U)
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)
DIMETHICONE (UNII: 92RU3N3Y1O)
GLUCONOLACTONE (UNII: WQ29KQ9POT)
GLYCERIN (UNII: PDC6A3C0OX)
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)
HYDROXYACETOPHENONE (UNII: G1L3HT4CMH)
ILEX PARAGUARIENSIS LEAF (UNII: 1Q953B4O4F)
IODOPROPYNYL BUTYLCARBAMATE (UNII: 603P14DHEB)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
POLYSORBATE 60 (UNII: CAL22UVI4M)
SODIUM BENZOATE (UNII: OJ245FE5EU)
SODIUM HYDROXIDE (UNII: 55X04QC32I)
SODIUM STEAROYL LACTYLATE (UNII: IN99IT31LN)
EDETATE SODIUM (UNII: MP1J8420LU)
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)
GRAPE SEED OIL (UNII: 930MLC8XGG)
WATER (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 not final	part348	03/12/2021	

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OTC monograph not final	part348	03/12/2021	

Labeler - RB Health (US) LLC (081049410)