

**BIOFREEZE ROLL-ON AND OVERNIGHT ROLL-ON- menthol
RB Health (US) LLC**

BioFreeze Day & Overnight Roll-On

Drug Facts

Roll-on/Overnight Roll-on:

Menthol 4%

Uses

Uses

Roll-on:

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

Uses

Overnight Roll-on:

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

Warnings

Roll-on:

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

Warnings

Overnight Roll-on:

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
- children 2 years to under 12 years of age: use only under adult supervision

Stop use and ask a doctor if

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- arthritic pain persists for more than 10 days, or redness is present, or in conditions affecting children under 12 years of age

Directions

Directions

Roll-on:

- 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

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Overnight Roll-on:

- adults and children 2 years of age and older: rub a thin film over affected area not more than 3 to 4 times daily
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Other Information

- store at 20-25°C (68-77°F)
- store in a cool dry place away from direct sunlight

Questions

Questions or comments? 1-800-246-3733

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.

Purpose:

Pain Relieving Gel

Roll-on:

Aloe Barbadensis Leaf Extract, Arctium Lappa Root (Burdock) Extract, Arnica Montana Flower Extract, Blue 1, 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, Yellow 5

Overnight Roll-on:

Alcohol, Aloe Barbadensis Leaf Extract, Arctium Lappa Root Extract, Arnica Montana Flower Extract, Boswellia Carterii Resin Extract, Calendula Officinalis Leaf Extract, Camellia Sinensis Leaf Extract, Carbomer Interpolymer, Colloidal Silicon Dioxide, Fragrance, Glycerin, Ilex Paraguariensis Leaf Extract, Isopropyl Alcohol, Melissa Officinalis Leaf Extract, Purified Water, Tocopherol Acetate, Trolamine



BIOFREEZE®

COOL THE PAIN

DAY & OVERNIGHT RELIEF



NDC 58316-209-14

BIOFREEZE®

COOL THE PAIN

DAY & OVERNIGHT RELIEF

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

USE ONLY AS DIRECTED. FOLLOW DRUG FACTS DIRECTIONS FOR EACH PRODUCT. DO NOT EXCEED 3 TO 4 APPLICATIONS TO THE AFFECTED AREA IN ANY 24-HOUR PERIOD. DO NOT APPLY BIOFREEZE ROLL-ON AND BIOFREEZE OVERNIGHT RELIEF ROLL-ON AT THE SAME TIME. RETAIN THIS CARTON FOR COMPLETE PRODUCT INFORMATION.

BIOFREEZE®

COOL THE PAIN

ROLL-ON

MENTHOL-PAIN RELIEVING GEL



Fast Acting, Long Lasting, Menthol Pain Relief for sore muscles and joints

OVERNIGHT RELIEF ROLL-ON

MENTHOL-PAIN RELIEVING GEL



Overnight Relief scented with Lavender

TWO - 2.5 FL OZ (74 mL) BOTTLES TOTAL 5 FL OZ (148 mL)

BIOFREEZE®

COOL THE PAIN

CONVENIENT ROLL-ON



EASY TO APPLY



MESS-FREE APPLICATION



ON-THE-GO TRAVEL FRIENDLY

*Based on a survey of Clinicians: chiropractors, podiatrists, physical therapists, massage therapists, retail pharmacists, and athletic trainers, who recommend OTC topical pain relief products (per Clinician Survey)

BIOFREEZE OVERNIGHT RELIEF ROLL-ON**BIOFREEZE ROLL-ON****Drug Facts**

Active ingredient Purpose
Menthol 4%.....Pain Relieving Gel

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

Warnings

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Other information

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- store in a cool dry place away from direct sunlight

Inactive ingredients

Alcohol, Aloe Barbadosis Leaf Extract, Arctium Lappa Root Extract, Arnica Montana Flower Extract, Boswellia Carterii Resin Extract, Calendula Officinalis Leaf Extract, Camellia Sinensis Leaf Extract, Carbomer Interpolymer, Colloidal Silicon Dioxide, Fragrance, Glycerin, Ilax Paraguariensis Leaf Extract, Isopropyl Alcohol, Melissa Officinalis Leaf Extract, Purified Water, Tocopherol Acetate, Tirolamine

Questions or comments? 1-800-246-3733

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Inactive ingredients

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Questions or comments? 1-800-246-3733

SHAKE WELL BEFORE EACH USE

©2026 RB Health
Dist. by: RB Health (US)
Parlinpeny, NJ 07054-0224
Does not contain NSAIDs,
Ibuprofen, Aspirin or Salicylate
www.biofreeze.com 3350907 012826

**VARNISH
FREE AREA**

BIOFREEZE ROLL-ON AND OVERNIGHT ROLL-ON

menthol kit

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:59316-209
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Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59316-209-14	2 in 1 KIT	04/01/2026	
1		1 in 1 BOTTLE; Type 9: Other Type of Part 3 Combination Product (e.g., Drug/Device/Biological Product)		

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	1 BOTTLE	74 mL
Part 2	1 BOTTLE	74 mL

Part 1 of 2

BIOFREEZE ROLL-ON

menthol gel

Product Information

Item Code (Source)	NDC:59316-205
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	40 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
ILEX PARAGUARIENSIS LEAF (UNII: 1Q953B4O4F)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
MELISSA OFFICINALIS LEAF (UNII: 50D2ZE9219)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
BLUE 1 (UNII: H3R47K3TBD)	
WATER (UNII: 059QF0KO0R)	
ARNICA MONTANA FLOWER (UNII: OZ0E5Y15PZ)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
TROLAMINE (UNII: 9O3K93S3TK)	

FRANKINCENSE (UNII: R9XLF1R1WM)
GLYCERIN (UNII: PDC6A3C0OX)
CALENDULA OFFICINALIS FLOWER (UNII: P0M7O4Y7YD)
CAMPHOR (NATURAL) (UNII: N20HL7Q941)
ALOE VERA LEAF (UNII: ZY81Z83H0X)
YELLOW 5 (UNII: I753WB2F1M)
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)
CARBOMER (UNII: 0A5MM307FC)
GREEN TEA LEAF (UNII: W2ZU1RY8B0)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59316-205-14	74 mL in 1 BOTTLE; 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	01/17/2013	

Part 2 of 2

BIOFREEZE OVERNIGHT ROLL-ON

menthol gel

Product Information

Item Code (Source)	NDC:59316-207
Route of Administration	TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	40 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
ARNICA MONTANA FLOWER (UNII: OZ0E5Y15PZ)	

GREEN TEA LEAF (UNII: WZZU1RY8B0)
FRANKINCENSE (UNII: R9XLF1R1WM)
ALOE VERA LEAF (UNII: ZY81Z83H0X)
CALENDULA OFFICINALIS FLOWER (UNII: P0M7O4Y7YD)
ARCTIUM LAPPA ROOT (UNII: 597E9BI3Z3)
CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO)
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)
MELISSA OFFICINALIS LEAF (UNII: 50D2ZE9219)
ALCOHOL (UNII: 3K9958V90M)
ILEX PARAGUARIENSIS LEAF (UNII: 1Q953B4O4F)
TROLAMINE (UNII: 9O3K93S3TK)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59316-207-14	74 mL in 1 BOTTLE; 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	03/16/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M017	04/01/2026	

Labeler - RB Health (US) LLC (081049410)