

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

BiOFREEZE ® Overnight Roll-on

Drug Facts

Active

Mentol USP 4%

Purpose

Pain Relieving Gel

Uses

Temporarily relieves minor aches and pains of muscles and joints associated with:

- simple backache
- arthritis
- strains
- bruises
- sprains

Warnings

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:

■ 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

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.

Directions**■ 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****Other Information****■ store at 20-25°C (68-77°F)****■ store in a cool dry place away from direct sunlight****Inactive Ingredients**

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

Questions or Comments

1-800-246-3733

SPL UNCLASSIFIED SECTION

Dist. by: RB Health (US), Parsippany, NJ 07054-0224

Principal Display Panel - 74 mL Bottle Label

CLINICALLY RECOMMENDED

NDC 59316-207-14

BIOFREEZE

COOL THE PAIN

ROLL-ON

MENTHOL- PAIN RELIEVING GEL

2.5 FL OZ (74mL)

SHAKE WELL BEFORE EACH USE



BIOFREEZE OVERNIGHT ROLL-ON

menthol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:59316-207
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)		MENTHOL	40 mg in 1 mL	
Inactive Ingredients				
Ingredient Name			Strength	
CALENDULA OFFICINALIS FLOWER (UNII: P0M7O4Y7YD)				
GLYCERIN (UNII: PDC6A3C0OX)				
GREEN TEA LEAF (UNII: W2ZU1RY8B0)				
FRANKINCENSE (UNII: R9XLF1R1WM)				
CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO)				
MELISSA OFFICINALIS LEAF (UNII: 50D2ZE9219)				
ALCOHOL (UNII: 3K9958V90M)				
ARNICA MONTANA FLOWER (UNII: OZ0E5Y15PZ)				
ALOE VERA LEAF (UNII: ZY81Z83H0X)				
ARCTIUM LAPPA ROOT (UNII: 597E9BI3Z3)				
ISOPROPYL ALCOHOL (UNII: ND2M416302)				
WATER (UNII: 059QF0KO0R)				
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)				
ILEX PARAGUARIENSIS LEAF (UNII: 1Q953B4O4F)				
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)				
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	03/16/2023	
Marketing Information				
Marketing Category		Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug		M017	03/16/2023	

Labeler - RB Health (US) LLC (081049410)

Revised: 12/2024

RB Health (US) LLC