BIOFREEZE COLORLESS ROLL-ON- menthol gel 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 Colorless Roll-On

Drug Facts

Active ingredient

Menthol 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

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

Aloe Barbadensis Leaf Extract, Arctium Lappa Root (Burdock) Extract, Arnica Montana Flower Extract, 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

Questions or comments?

1-800-246-3733

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

PRINCIPAL DISPLAY PANEL - 89 mL Bottle Label

CLINICALLY RECOMMENDED*

NDC 59316-206-10

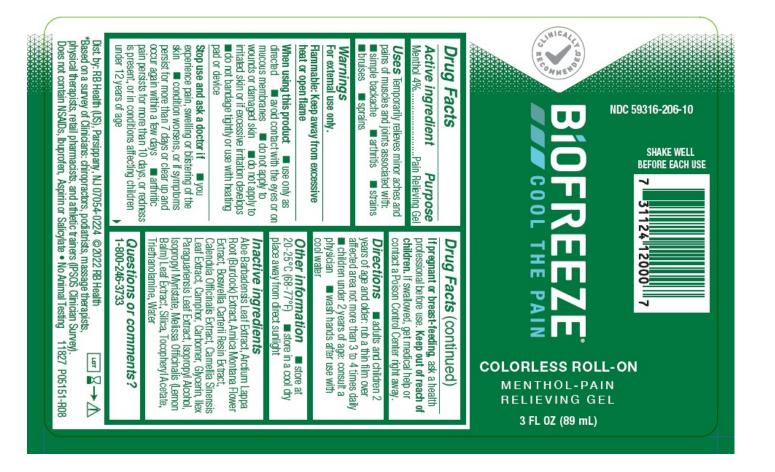
BiOFREEZE® COOL THE PAIN

SHAKE WELL BEFORE EACH USE

COLORLESS ROLL-ON

MENTHOL-PAIN RELIEVING GEL

3 FL OZ (89 mL)



BIOFREEZE COLORLESS ROLL-ON

menthol gel

Product Information	roduct Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:59316-206	
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, UNS PECIFIED FORM	40 mg in 1 mL	

Inactive Ingredients		
Ingredient Name	Strength	
ALOE VERA LEAF (UNII: ZY81Z83H0X)		
ARCTIUM LAPPA ROOT (UNII: 597E9BI3Z3)		
ARNICA MONTANA FLOWER (UNII: OZ0E5Y15PZ)		
FRANKINCENSE (UNII: R9XLF1R1WM)		
CALENDULA OFFICINALIS FLOWER (UNII: POM7O4Y7YD)		
GREEN TEA LEAF (UNII: W2ZU1RY8B0)		
CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)		
GLYCERIN (UNII: PDC6A3C0OX)		

ILEX PARAGUARIENSIS LEAF (UNII: 1Q953B4O4F)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
MELISSA OFFICINALIS LEAF (UNII: 50D2ZE9219)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
.ALPHATOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
TROLAMINE (UNII: 903K93S3TK)	
WATER (UNII: 059QF0KO0R)	

Pā	Packaging Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	NDC:59316- 206-10	1 in 1 CARTON	01/17/2013	
1		89 mL in 1 BOTTLE, WTH APPLICATOR; 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	01/17/2013	

Labeler - RB Health (US) LLC (081049410)

Revised: 1/2022 RB Health (US) LLC