# BIOFREEZE PROFESSIONAL COLORLESS ROLL-ON- menthol, unspecified form 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.

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### **Biofreeze Professional Colorless Roll-On**

## **Drug Facts**

## **Active ingredient**

Menthol 5%

## **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, 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 59316-118-10

SHAKE WELL BEFORE EACH USE

BiOFREEZE® PROFESSIONAL

COLORLESS ROLL-ON MENTHOL-PAIN RELIEVING GEL

3 FL OZ (89 mL)

"Based on a survey of Clinicians: chiropractors, podiatrists, massage therapists, physical therapists, retail pharmacists, and athletic trainers (IPSOS Clinician Survey) Dist. by: RB Health (US), Parsippany, NJ 07054-0224 @2022 RB Health Does not contain NSAIDs, Ibuprofen, Aspirin or Salicylate 

No Animal Testing wounds or damaged skin do not apply to irritated skin or if excessive irritation develops ■ simple backache
■ bruises
■ spra is present, or in conditions affecting children occur again within a few days arthritic pain persists for more than 10 days, or redness persist for more than 7 days or clear up and occur again within a few days arthritic experience pain, swelling or blistering of the Stop use and ask a doctor if pag or gevice do not bandage tightly or use with heating mucous membranes directed When using this product Flammable: Keep away from excessive under 12 years of age heat or open flame For external use only Warnings pains of muscles and Uses Temporarily relieves minor aches and Active ingredient Drug Facts condition worsens, or it symptoms avoid contact with the eyes or on sprains arthritis joints associated with: do not apply to use only as you Purpose strains physician cool water children under 2 years of age: consult a professional before use. Keep out of reach of children. If swallowed, get medical help or If pregnant or breast-feeding, ask a health Drug Isopropyl Myristate, Melissa Officinalis (Lemon Balm) Leaf Extract, Silica, Tocopheryl Acetate, Directions Root (Burdock) Extract, Arnica Montana Flower place away from direct sunligh: 20-25°C (68-77°F) affected area not more than 3 to 4 times daily years of age and older: rub a thin film over Questions or comments? Paraguariensis Leaf Extract, Isopropyl Alcohol \_eaf Extract, Carbomer, Glycerin, llex extract, Boswellia Carterii Resin Extract Aloe Barbadensis Leat Inactive ingredients Other information contact a Poison Control Center right away -800-246-3733 alendula Officinalis Extract, Camella Sinensis iethanolamine, Water Facts ■ wash hands after use with adults and children ? (continued store in a cool dry Extract, Arctium Lappa 13419 P07883-R04

NDC 59316-118-10 SHAKE WELL BEFORE EACH USE 9316"11810" 8 COLORLESS ROLL-ON MENTHOL-PAIN RELIEVING GEL

3 FL 0Z (89 mL)

## **BIOFREEZE PROFESSIONAL COLORLESS ROLL-ON**

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menthol, unspecified form gel

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#### **Product Information HUMAN OTC DRUG** NDC:59316-118 **Product Type** Item Code (Source) **TOPICAL Route of Administration**

Active Ingredient/Active Moiety						
Ingredient Name	<b>Basis of Strength</b>	Strength				
MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A) (MENTHOL, UNSPECIFIED FORM - UNII:L7T10EIP3A)	MENTHOL, UNSPECIFIED FORM	50 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: P0M7O4Y7YD)		
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)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	NDC:59316-118- 10	89 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/03/2016	

Marketing Information				
Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
part348	06/03/2016			
	Application Number or Monograph Citation	Application Number or Monograph Marketing Start Citation Date		

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

Revised: 1/2022 RB Health (US) LLC