BIOFREEZE PROFESSIONAL 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.

Biofreeze® Professional 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, Blue 1, 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, Yellow 5

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 59316-117-10

SHAKE WELL BEFORE EACH USE

BiOFREEZE® PROFESSIONAL

ROLL-ON MENTHOL-PAIN RELIEVING GEL

3 FL OZ (89 mL)

Based on a survey of Clinicians: chiropractors, podfatrists, massage therapists, physical therapists, retail pharmacists, and athletic trainers (IPSOS Clinician Survey Does not contain NSAIDs, Dist. by: RB Health (US), Parsippany, NJ 07054-0224 ©2022 RB Health experience pain, swelling or blistering of the under 12 years of age is present, or in conditions affecting children pain persists for more than 10 days, or redness occur again within a few days persist for more than / days or clear up and condition worsens, or if symptoms buprofen, Aspirin or Salicylate

No Animal Testing ■ arthritic Questions or 1-800-246-3733 sopropyl Myristate, Melissa Officinalis (Lemor riethanolamine, Water, araguariensis Leaf Extract, Isopropyl Alcoho Leaf Extract, Silica,

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SHAKE WELL **BEFORE EACH USE**



ROLL-ON MENTHOL-PAIN RELIEVING GEL 3 FL 0Z (89 mL)

Drug Facts

Drug

Facts

(continued

Active ingredient

Purpose

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physician children under 2 years of age: consult a affected area not more than 3 to 4 times dail wash hands after use with adults and children 2 film over

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comments?

Tocopheryl Acetate,

BIOFREEZE PROFESSIONAL ROLL-ON

Root (Burdock) Extract, Arnica Montana Flower Extract, Blue 1, Boswellia Carterii Resin Extract

Calendula Officinalis Extract, Camellia Sinensis

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menthol, unspecified form gel

Product Information

HUMAN OTC DRUG NDC:59316-117 **Product Type** Item Code (Source)

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name Basis of Strength Strength MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A) (MENTHOL, UNSPECIFIED 50 mg FORM - UNII:L7T10EIP3A) **UNSPECIFIED FORM** in 1 mL

Inactive Ingredients			
Ingredient Name	Strength		
ALOE VERA LEAF (UNII: ZY81Z83H0X)			
ARCTIUM LAPPA ROOT (UNII: 597E9BI3Z3)			
ARNICA MONTANA FLOWER (UNII: OZ0E5Y15PZ)			
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)			
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: ORE8K4LNJS)	
MELISSA OFFICINALIS LEAF (UNII: 50D2ZE9219)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
.ALPHATOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
TROLAMINE (UNII: 903K93S3TK)	
WATER (UNII: 059QF0KO0R)	
FD&C YELLOW NO. 5 (UNII: 1753WB2F1M)	

P	Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:59316-117- 10	89 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/03/2016			

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part348	06/03/2016		

Labeler - RB Health (US) LLC (081049410)

Revised: 1/2022 RB Health (US) LLC