

**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)



NDC 59316-117-10

SHAKE WELL BEFORE EACH USE



BIOFREEZE PROFESSIONAL

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

Drug Facts

Active ingredient Purpose Menthol 5% Pain Relieving Gel

Uses Temporarily relieves minor aches and pains of muscles and joints associated with: simple headache, 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

Drug Facts (continued)

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 Barbadosis 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 ©2022 RB Health. Based on a survey of Clinicians: chiropractors, podiatrists, massage therapists, physical therapists, retail pharmacists, and athletic trainers (PSOS Clinician Survey). Does not contain NSAIDs, Ibuprofen, Aspirin or Salicylate • No Animal Testing 13416 P07881-R05



BIOFREEZE PROFESSIONAL ROLL-ON

menthol, unspecified form gel

Product Information

Table with Product Type (HUMAN OTC DRUG), Item Code (Source) (NDC:59316-117), and Route of Administration (TOPICAL)

Active Ingredient/Active Moiety

Table with columns: Ingredient Name, Basis of Strength, Strength. Row: MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A) (MENTHOL, UNSPECIFIED FORM - UNII:L7T10EIP3A), MENTHOL, UNSPECIFIED FORM, 50 mg in 1 mL

Inactive Ingredients

Table with columns: Ingredient Name, Strength. Lists various inactive ingredients like ALOE VERA LEAF, ARCTIUM LAPPA ROOT, etc.

<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>ILEX PARAGUARIENSIS LEAF</b> (UNII: 1Q953B4O4F)	
<b>ISOPROPYL ALCOHOL</b> (UNII: ND2M416302)	
<b>ISOPROPYL MYRISTATE</b> (UNII: 0RE8K4LNJS)	
<b>MELISSA OFFICINALIS LEAF</b> (UNII: 50D2ZE9219)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>.ALPHA.-TOCOPHEROL ACETATE</b> (UNII: 9E8X80D2L0)	
<b>TROLAMINE</b> (UNII: 9O3K93S3TK)	
<b>WATER</b> (UNII: 059QF0KOOR)	
<b>FD&amp;C YELLOW NO. 5</b> (UNII: I753WB2F1M)	

### 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