

**BIOFREEZE PROFESSIONAL COLORLESS ROLL-ON- menthol, unspecified form gel**  
**Performance Health, 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 Ingredients:***

Menthol USP 5%

**Purpose**

Cooling Pain Relief

**Uses:**

Temporary relief from minor aches and pains of sore muscles and joints associated with arthritis, backache, strains and sprains

***Warnings:***

**For external use only**

**Flammable:** Keep away from excessive heat or open flame

**Ask a doctor before use if you have:**

Sensitive skin

**When using this product:**

Avoid contact with the eyes or mucous membranes; Do not apply to wounds or damaged skin; Do not use with other ointments, creams, sprays or liniment; Do not apply to irritated skin or if excessive irritation develops; Do not bandage; Wash hands after use with cool water; Do not use with heating pad or device; Store in cool dry place

**Stop use and ask a doctor If:**

Condition worsens, or if symptoms persist for more than 7 days , or clear up and recur

**If pregnant or breast-feeding:**

Ask a health professional before use

**Keep out of reach of children:**

If accidentally ingested, get medical help or contact a Poison Control Center immediately

***Directions:***

**Adults and Children 2 years of age and older:** Rub a thin film over affected areas not more four times daily; massage not necessary **Children under 2 years of age:** Consult physician

## 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

## Package Labeling: 59316-118-10

**Cold therapy pain relief for sore muscles, backaches, sore joints and arthritis**  
VANISHING SCENT • PARABEN-FREE

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|                            |                     |
|----------------------------|---------------------|
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SHAKE WELL  
BEFORE EACH USE

BIOFREEZE

PROFESSIONAL

#1


COLORLESS ROLL-ON

LONGER LASTING<sup>+</sup>  
MENTHOL PAIN RELIEF


3 FL. OZ. / 89mL

\*Trusted by pharmacists, physical therapists, chiropractors, massage therapists and podiatrists. Biofreeze® Professional Roll-on is backed by 25 years of scientific research and clinician use and is specially formulated to last longer.

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1245 Home Avenue, Akron, OH 44310  
www.biofreeze.com



1,3419 REV3  
Manufactured in the USA  
No Animal Testing  
Does not contain NSAIDs,  
Ibuprofen, Aspirin, or Salicylate

LOT 

+ Lasts longer than regular Biofreeze®

## BIOFREEZE PROFESSIONAL COLORLESS ROLL-ON

menthol, unspecified form gel

### Product Information

|                                |                |                           |               |
|--------------------------------|----------------|---------------------------|---------------|
| <b>Product Type</b>            | HUMAN OTC DRUG | <b>Item Code (Source)</b> | NDC:59316-118 |
| <b>Route of Administration</b> | TOPICAL        |                           |               |

### Active Ingredient/Active Moiety

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

## Inactive Ingredients

| Ingredient Name                                 | Strength |
|---|----------|
| ALOE VERA LEAF (UNII: ZY81Z83H0X)               |          |
| ARCTIUM LAPPA ROOT (UNII: 597E9B13Z3)           |          |
| ARNICA MONTANA FLOWER (UNII: OZ0E5Y15PZ)        |          |
| FRANKINCENSE (UNII: R9XLF1R1WM)                 |          |
| CALENDULA OFFICINALIS FLOWER (UNII: P0M7O4Y7YD) |          |
| GREEN TEA LEAF (UNII: W2ZU1RY8B0)               |          |
| CARBOXYPOLYMETHYLENE (UNII: 0A5MM307FC)         |          |
| GLYCERIN (UNII: PDC6A3C0OX)                     |          |
| ILEX PARAGUARIENSIS LEAF (UNII: 1Q953B404F)     |          |
| ISOPROPYL ALCOHOL (UNII: ND2M416302)            |          |
| ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)          |          |
| MELISSA OFFICINALIS LEAF (UNII: 50D2ZE9219)     |          |
| SILICON DIOXIDE (UNII: ETJ7Z6XBU4)              |          |
| .ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)   |          |
| TROLAMINE (UNII: 9O3K93S3TK)                    |          |
| WATER (UNII: 059QF0K00R)                        |          |

## Packaging

| # | Item Code        | Package Description                                  | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:59316-118-10 | 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** - Performance Health, LLC (794324061)