

**BIOFREEZE PRECISION RELIEF PEN- menthol liquid**  
**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® Precision Relief Pen**

**Drug Facts**

**Active ingredient**

Menthol 10.5%

**Purpose**

Pain Relieving Liquid

**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

**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 12 years of age and older: shake well before use. Press pen straight down onto affected area and hold until tip is fully soaked with liquid. Using light pressure, dab onto skin and let dry. Apply to affected area not more than 3 to 4 times daily; massage not necessary
- children under 12 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**

Alcohol Denat., Arnica Montana Flower Extract, Calendula Officinalis Flower Extract, Camellia Sinensis Leaf Extract, Chamomilla Recutita (Matricaria) Flower Extract, Dimethyl Sulfone (MSM), Echinacea Angustifolia Extract, Ilex Paraguariensis Leaf Extract, Isopropyl Myristate, Juniperus Communis Fruit Extract, Water

### **Questions or comments?**

1-800-246-3733

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

### **PRINCIPAL DISPLAY PANEL - 34 mL Bottle Carton**

NDC 59316-830-38

BiOFREEZE®

COOL THE PAIN

PRECISION RELIEF PEN

MENTHOL-PAIN RELIEVING LIQUID

1.15 FL OZ (34 mL)

**BIOFREEZE**  
COOL THE PAIN

1 PRECISION RELIEF PEN



NDC 59316-830-38

**BIOFREEZE**  
COOL THE PAIN

**BIOFREEZE**  
COOL THE PAIN

COLD THERAPY PAIN RELIEF FOR SORE  
MUSCLES, JOINTS, SIMPLE BACKACHES,  
ARTHRITIS, STRAINS, BRUISES AND SPRAINS.

**Drug Facts**

**Active ingredient** *Purpose*  
Menthol 10.5% ..... Pain Relieving Liquid

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No Animal Testing  
Does not contain NSAIDs,  
Ibuprofen, Aspirin or Salicylate

www.biofreeze.com  
15106 P11409-P01



Knockout Area  
Does not print

**BIOFREEZE**  
COOL THE PAIN

PRECISION  
RELIEF  
PEN



PRECISION  
APPLICATION



GOES ON  
CLEAR



GREAT FOR  
JOINT PAIN



HOW TO  
USE



Shake



Press



Apply

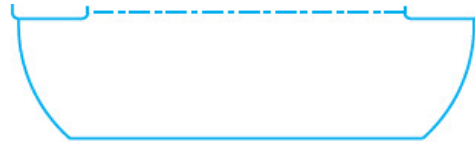
See back panel for more detailed directions. Keep carton for full information.

PRECISION RELIEF PEN  
MENTHOL-PAIN RELIEVING LIQUID  
1.15 FL OZ (34 mL)

\*Based on a survey of Clinicians: chiropractors, podiatrists, massage therapists, physical therapists, retail pharmacists, and athletic trainers (PSOS Clinician Survey).



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## BIOFREEZE PRECISION RELIEF PEN

menthol liquid

### Product Information

|                                |                |                           |               |
|--------------------------------|----------------|---------------------------|---------------|
| <b>Product Type</b>            | HUMAN OTC DRUG | <b>Item Code (Source)</b> | NDC:59316-830 |
| <b>Route of Administration</b> | TOPICAL        |                           |               |

### Active Ingredient/Active Moiety

| Ingredient Name   | Basis of Strength         | Strength          |
|---|---------------------------|-------------------|
| <b>MENTHOL, UNSPECIFIED FORM</b> (UNII: L7T10EIP3A) (MENTHOL, UNSPECIFIED FORM - UNII:L7T10EIP3A) | MENTHOL, UNSPECIFIED FORM | 105 mg<br>in 1 mL |

### Inactive Ingredients

| Ingredient Name  | Strength |
|--|----------|
| <b>ALCOHOL</b> (UNII: 3K9958V90M)                      |          |
| <b>ARNICA MONTANA FLOWER</b> (UNII: OZ0E5Y15PZ)        |          |
| <b>CALENDULA OFFICINALIS FLOWER</b> (UNII: P0M7O4Y7YD) |          |
| <b>GREEN TEA LEAF</b> (UNII: W2ZU1RY8B0)               |          |
| <b>CHAMOMILE</b> (UNII: FGL3685T2X)                    |          |
| <b>DIMETHYL SULFONE</b> (UNII: 9H4PO4Z4FT)             |          |
| <b>ECHINACEA ANGUSTIFOLIA WHOLE</b> (UNII: VB06AV5US8) |          |
| <b>ILEX PARAGUARIENSIS LEAF</b> (UNII: 1Q953B4O4F)     |          |
| <b>ISOPROPYL MYRISTATE</b> (UNII: 0RE8K4LNJS)          |          |
| <b>JUNIPER BERRY</b> (UNII: O84B5194RL)                |          |
| <b>WATER</b> (UNII: 059QF0KO0R)                        |          |

### Packaging

| # | Item Code        | Package Description                                  | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:59316-830-37 | 34 mL in 1 BOTTLE; Type 0: Not a Combination Product | 12/31/2020           |                    |
| 2 | NDC:59316-830-38 | 1 in 1 CARTON  | 12/31/2020           |                    |
| 2 |                  | 34 mL in 1 BOTTLE; 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

12/31/2020

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

Revised: 1/2022

RB Health (US) LLC