**BIOFREEZE- menthol gel**
**RB Health (US) LLC**

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**BiOFREEZE ®**

***Drug Facts***

***Active Ingredients:***

Menthol USP 4%

***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 breastfeeding:**

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, Camphor, 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 - 473 mL Bottle Label**

CLINICALLY
RECOMMENDED ®

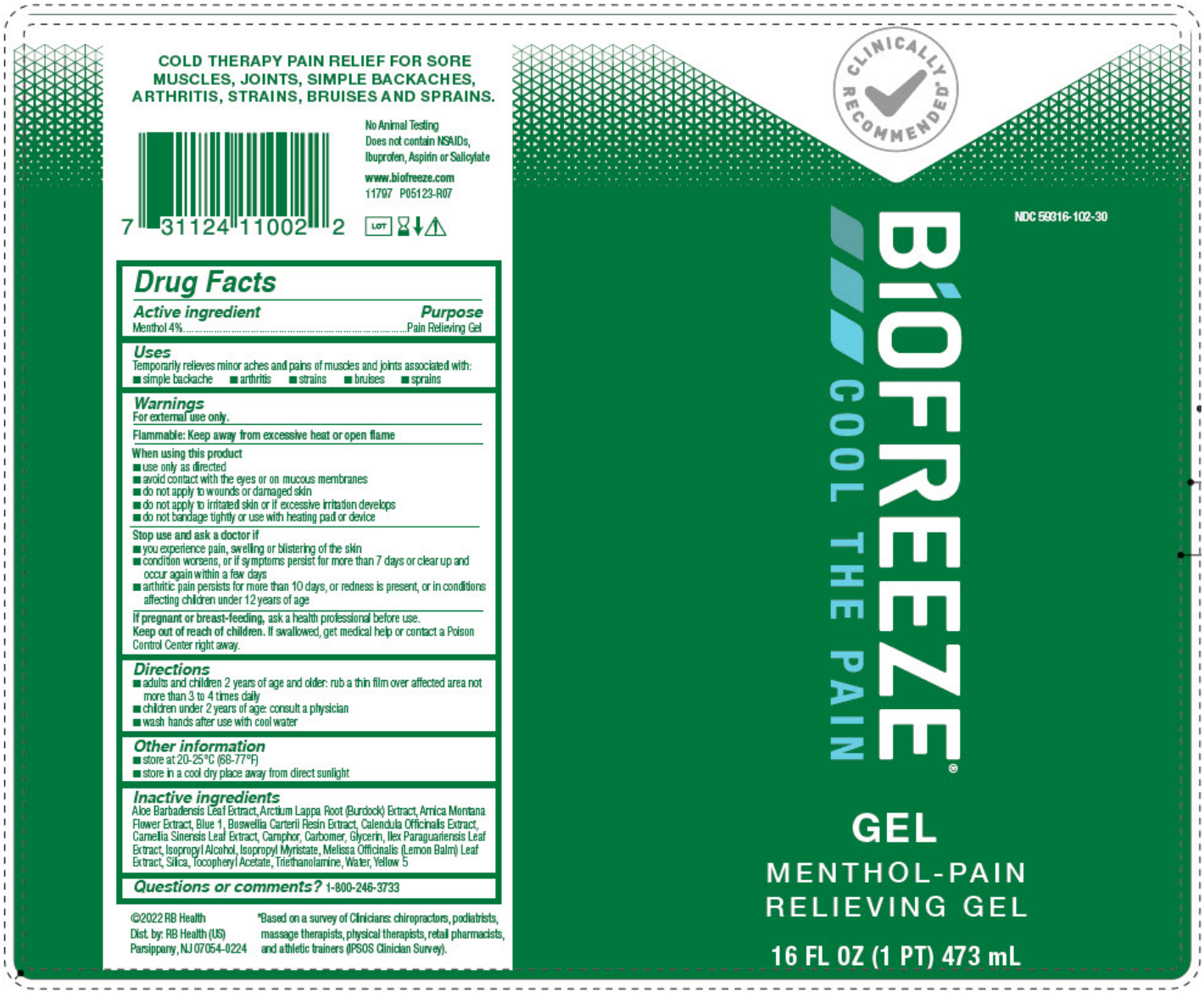
NDC 59316-102-30

BiOFREEZE ®
COOL THE PAIN

GEL

MENTHOL-PAIN
RELIEVING GEL

16 FL OZ (1 PT) 473 mL




# BIOFREEZE

menthol gel

| Product Information | | | |
|---|---|---|---|
| **Product Type** | HUMAN OTC DRUG | **Item Code (Source)** | NDC:59316-102 |
| **Route of Administration** | TOPICAL | | |

| Active Ingredient/Active Moiety | | |
|---|---|---|
| **Ingredient Name** | **Basis of Strength** | **Strength** |
| **MENTHOL, UNSPECIFIED FORM** (UNII: L7T10EIP3A) (MENTHOL, UNSPECIFIED FORM - UNII:L7T10EIP3A) | MENTHOL, UNSPECIFIED FORM | 40 mg in 1 mL |

| Inactive Ingredients | |
|---|---|
| **Ingredient Name** | **Strength** |

| | |
|---|---|
| **.ALPHA.-TOCOPHEROL ACETATE** (UNII: 9E8X80D2L0) | |
| **ALOE VERA LEAF** (UNII: ZY81Z83H0X) | |
| **ARNICA MONTANA FLOWER** (UNII: OZ0E5Y15PZ) | |
| **ARCTIUM LAPPA ROOT** (UNII: 597E9BI3Z3) | |
| **FRANKINCENSE** (UNII: R9XLF1R1WM) | |
| **CALENDULA OFFICINALIS FLOWER** (UNII: P0M7O4Y7YD) | |
| **GREEN TEA LEAF** (UNII: W2ZU1RY8B0) | |
| **CAMPHOR (SYNTHETIC)** (UNII: 5TJD82A1ET) | |
| **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) | |
| **TROLAMINE** (UNII: 9O3K93S3TK) | |
| **WATER** (UNII: 059QF0KO0R) | |
| **FD&C BLUE NO. 1** (UNII: H3R47K3TBD) | |
| **FD&C YELLOW NO. 5** (UNII: I753WB2F1M) | |

## Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|---|---|---|---|
| **1** | NDC:59316-102-10 | 5 mL in 1 BOTTLE; Type 0: Not a Combination Product | 01/03/2012 | |
| **2** | NDC:59316-102-11 | 3 mL in 1 BOTTLE; Type 0: Not a Combination Product | 01/03/2012 | |
| **3** | NDC:59316-102-15 | 89 mL in 1 BOTTLE, WITH APPLICATOR; Type 0: Not a Combination Product | 01/03/2012 | 12/31/2018 |
| **4** | NDC:59316-102-20 | 118 mL in 1 BOTTLE; Type 0: Not a Combination Product | 01/03/2012 | |
| **5** | NDC:59316-102-25 | 118 mL in 1 BOTTLE, WITH APPLICATOR; Type 0: Not a Combination Product | 01/03/2012 | 12/31/2021 |
| **6** | NDC:59316-102-30 | 473 mL in 1 BOTTLE; Type 0: Not a Combination Product | 01/03/2012 | |
| **7** | NDC:59316-102-40 | 946 mL in 1 BOTTLE; Type 0: Not a Combination Product | 01/03/2012 | |
| **8** | NDC:59316-102-50 | 3785 mL in 1 CONTAINER; Type 0: Not a Combination Product | 01/03/2012 | |
| **9** | NDC:59316-102-98 | 30 mL in 1 BOTTLE; Type 0: Not a Combination Product | 01/03/2012 | |
| **10** | NDC:59316-102-80 | 44 mL in 1 TUBE; Type 0: Not a Combination Product | 11/02/2018 | |
| **11** | NDC:59316-102-12 | 89 mL in 1 BOTTLE; Type 0: Not a Combination Product | 09/19/2016 | |
| **12** | NDC:59316-102-16 | 89 mL in 1 BOTTLE, WITH APPLICATOR; Type 0: Not a Combination Product | 09/19/2016 | 12/31/2019 |
| **13** | NDC:59316-102-28 | 237 mL in 1 BOTTLE; Type 0: Not a Combination Product | 09/19/2016 | |
| **14** | NDC:59316-102-90 | 100 in 1 CARTON | 01/03/2012 | |
| **14** | NDC:59316-102-10 | 5 mL in 1 BOTTLE; Type 0: Not a Combination Product | | |
| **15** | NDC:59316-102-91 | 10 in 1 CARTON | 01/03/2012 | 12/31/2025 |

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|---|---|---|---|---|
| **15** | NDC:59316-102-11 | 3 mL in 1 BOTTLE; Type 0: Not a Combination Product | | |
| **16** | NDC:59316-102-92 | 16 in 1 CARTON | 01/03/2012 | 12/31/2025 |
| **16** | NDC:59316-102-11 | 3 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 Drug | M017 | 01/03/2012 | |

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

Revised: 11/2023 RB Health (US) LLC