BIOFREEZE- menthol gel
RB Health (US) LLC

Biofreeze Pain Relieving Gel

Active Ingredients

Menthol USP 3.5%

Purpose

Cooling Pain Reliever

Uses

Temporary relief from minor aches and pains of sore muscles and joints associated with: arthritis - backache - strains - sprain

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 liniments
- 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

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 breastfeeding:

Ask a health professional before use.

Keep out of the 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 than 4 times daily; massage not necessary.
- Children under 2 years of age : Consult physician

Other Information:

Store in a cool dry place with lid closed tightly

Inactive ingredients

- carbomer, FD and C blue # 1, FD and C yellow # 5, glycerine, herbal extract (Ilex paraguariensis), isopropyl alcohol USP, methylparaben, natural camphor USP (for scent), propylene glycol, silicon dioxide, triethanolamine, purified water USP

Questions or Comments?

800-246-3733

PRINCIPAL DISPLAY PANEL - 89 mL Bottle Applicator Label

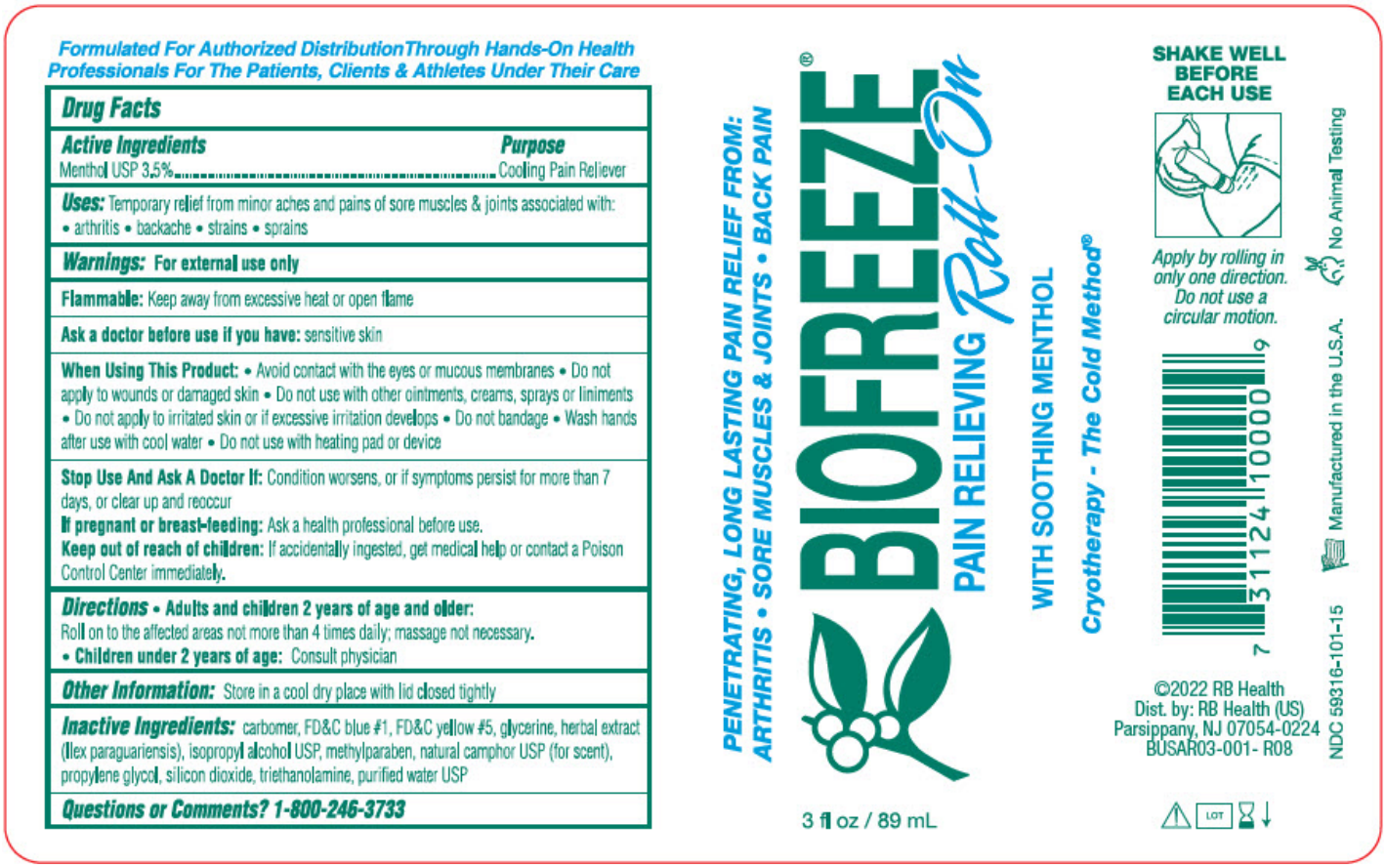
PENETRATING, LONG LASTING PAIN RELIEF FROM:
ARTHITIS • SORE MUSCLES & JOINTS • BACK PAIN

BIOFREEZE ®
PAIN RELIEVING Roll-On

WITH SOOTHING MENTHOL

Cryotherapy - The Cold Method ®

3 fl oz / 89 mL



PRINCIPAL DISPLAY PANEL - 473 mL Bottle Pump Label

PENETRATING, LONG LASTING PAIN RELIEF FROM:
ARTHITIS • SORE MUSCLES & JOINTS • BACK PAIN

BIOFREEZE ®
PAIN RELIEVING gel

WITH SOOTHING MENTHOL

Cryotherapy - The Cold Method ®

16 fl oz / 473 mL

Formulated For Authorized Distribution Through Hands-On Health Professionals For The Patients, Clients & Athletes Under Their Care.

Drug Facts

Active Ingredients — **Purpose**
Menthol USP 3.5% ..... Cooling Pain Reliever

Uses
Temporary relief from minor aches and pains of sore muscles & joints associated with: • arthritis • backache • strains • 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 liniments
- 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

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 than 4 times daily; massage not necessary.
- **Children under 2 years of age:** Consult physician

Other Information: Store in a cool dry place with lid closed tightly

Inactive Ingredients: carbomer, FD&C blue #1, FD&C yellow #5, glycerine, herbal extract (Ilex paraguariensis), isopropyl alcohol USP, methylparaben, natural camphor USP (for scent), propylene glycol, silicon dioxide, triethanolamine, purified water USP

Questions or Comments? 800-246-3733

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Dist. by: RB Health (US)
Parsippany, NJ 07054-0224
BUSAP16-001-R05
NDC 59316-101-30

Manufactured in the U.S.A.
No Animal Testing

LOT

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BIOFREEZE
menthol gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:59316-101
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	35 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
GLYCERIN (UNII: PDC6A3C0OX)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
CAMPHOR (NATURAL) (UNII: N20HL7Q941)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
TROLAMINE (UNII: 9O3K93S3TK)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59316-101-10	5 mL in 1 PACKET; Type 0: Not a Combination Product	08/25/2016	
2	NDC:59316-101-15	89 mL in 1 BOTTLE, WITH APPLICATOR; Type 0: Not a Combination Product	08/25/2016	
3	NDC:59316-101-20	118 mL in 1 TUBE; Type 0: Not a Combination Product	08/25/2016	
4	NDC:59316-101-21	81 mL in 1 TUBE; Type 0: Not a Combination Product	08/25/2016	12/31/2018
5	NDC:59316-101-30	473 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	08/25/2016	
6	NDC:59316-101-40	946 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	08/25/2016	
7	NDC:59316-101-50	3785 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	08/25/2016	
8	NDC:59316-101-25	118 mL in 1 TUBE, WITH APPLICATOR; Type 0: Not a Combination Product	08/25/2016	12/31/2021
9	NDC:59316-101-12	59 mL in 1 TUBE; Type 0: Not a Combination Product	08/25/2016	
10	NDC:59316-101-13	59 mL in 1 BOTTLE, WITH APPLICATOR; Type 0: Not a Combination Product	08/25/2016	
11	NDC:59316-101-11	30 mL in 1 BOTTLE; Type 0: Not a Combination Product	08/25/2016	
12	NDC:59316-101-19	3 mL in 1 PACKET; Type 0: Not a Combination Product	01/01/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M017	08/25/2016	

Labeler - RB Health (US) LLC (081049410)

Establishment

Name	Address	ID/FEI	Business Operations
Span Packaging Services dba Multi-Pack Solutions		557434805	manufacture(59316-101)

Revised: 12/2024

RB Health (US) LLC