BIOFREEZE- menthol 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 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

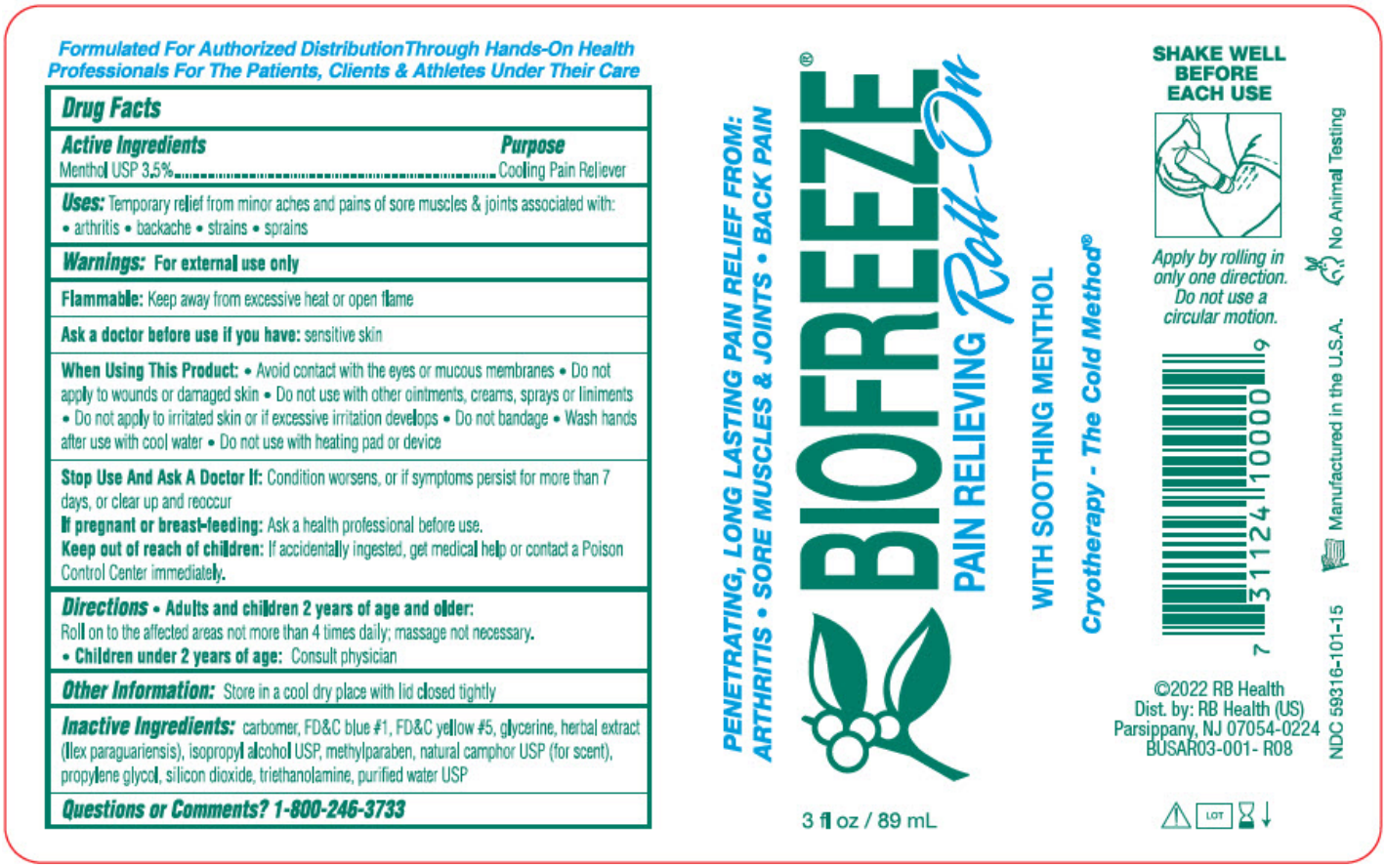
PENETRATING, LONG LASTING PAIN RELIEF FROM:
ARTHITIS • SORE MUSCLES & JOINTS • BACK PAIN

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

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 not final	part348	08/25/2016	

Labeler - RB Health (US) LLC (081049410)

Establishment

Name	Address	ID/FEI	Business Operations
Span Packaging Services dba Multi-Pack Solutions		117101131	manufacture(59316-101)

Establishment

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

Revised: 2/2022 RB Health (US) LLC