

BIOFREEZE- menthol spray
RB Health (US) LLC

Biofreeze Pain Relieving Spray

Drug Facts

Active Ingredients:

Menthol USP 10%

Purpose

Cooling Pain Reliever

Uses:

Temporary relief from minor aches and pains of sore muscles and 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 damages 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 reoccur

If pregnant or breastfeeding:

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 12 years of age and older: Spray on to the affected areas not more than 4 times daily; massage not necessary.

Children under 12 years of age: Consult a physician

Other Information:

Store in a cool dry place with lid closed tightly

Inactive Ingredients:

Arnica Montana, Calendula, Chamomile, Dimethyl Sulfone, Echinacea, Ethanol, Ilex Paraguarenis, Isopropyl Myristate, Juniper Berry, water, White Tea

Questions or Comments?

1-800-246-3733

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

PRINCIPAL DISPLAY PANEL - 473 mL Bottle Label

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

BIOFREEZE[®]

PAIN RELIEVING Spray

WITH SOOTHING MENTHOL

Cryotherapy - The Cold Method[®]

16 fl. oz./473mL

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

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Active Ingredients	Purpose
Menthol USP 10%.....	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 reoccur If pregnant or breastfeeding: 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 12 years of age and older: Spray on to the affected areas not more than 4 times daily; massage not necessary. • Children under 12 years of age: Consult physician	
Other Information: Store in a cool dry place with lid closed tightly	
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Questions or Comments? 1-800-246-3733	

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



16 fl. oz./473mL

WITH SOOTHING MENTHOL
Cryotherapy - The Cold Method®

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Dist. by: RB Health (US), Parsippany, NJ 07054-0224
BUSASNH16-001-R05 • NDC 59316-104-30



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

BIOFREEZE
menthol spray

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:59316-104
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	100 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
ARNICA MONTANA WHOLE (UNII: O80TY208ZW)	

CALENDULA OFFICINALIS FLOWER (UNII: P0M7O4Y7YD)
CHAMOMILE (UNII: FGL3685T2X)
DIMETHYL SULFOXIDE (UNII: YOW8V9698H)
ECHINACEA, UNSPECIFIED (UNII: 4N9P6CC1DX)
ALCOHOL (UNII: 3K9958V90M)
ILEX PARAGUARIENSIS LEAF (UNII: 1Q953B4O4F)
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)
JUNIPERUS COMMUNIS WHOLE (UNII: 464910T5N9)
WATER (UNII: 059QF0KO0R)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59316-104-10	59 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	08/25/2016	
2	NDC:59316-104-20	118 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	08/25/2016	
3	NDC:59316-104-30	473 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	08/25/2016	
4	NDC:59316-104-25	118 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	11/29/2012	12/31/2018

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M017	11/01/2010	

Labeler - RB Health (US) LLC (081049410)

Establishment

Name	Address	ID/FEI	Business Operations
Span Packaging services LLC dba Multi-Pack Solutions		117101131	manufacture(59316-104)

Establishment

Name	Address	ID/FEI	Business Operations
Span Packaging Services LLC dba Multi-Pack Solutions		557434805	manufacture(59316-104)

Revised: 1/2024

RB Health (US) LLC