

BIOFREEZE- menthol spray

Performance Health LLC

Reference Label Set Id: 44348c53-b600-4189-a797-379523b87480

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 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 / Children 12 years and older: Apply on to affected area up to 4 times daily

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 (MSM), Echinacea, Ethanol, Lex Paraguanensis, Isopropyl Myristate, Juniper Berry, Purified Water USP, White Tea

Questions or Comments?

1-800-246-3733

BIOFREEZE - menthol spray (59316-104-10)

Drug Facts	
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	
Inactive Ingredients: Arnica Montana, Calendula, Chamomile, Dimethyl Sulfone (MSM), Echinacea, Ethanol, Ilex Paraguariensis, Isopropyl Myristate, Juniper Berry, Purified Water USP, White Tea	

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

BIOFREEZE
PAIN RELIEVING Spray

WITH SOOTHING MENTHOL

Cryotherapy - The Cold Method®

©2010 Performance Health, LLC, Akron, OH 44310
BUSASN02-001 • REV 6 • NDC 59316-104-10
Questions or Comments? 1-800-246-3733

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

2 fl oz / 59 mL

LOT

BIOFREEZE - menthol spray (59316-104-30)

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

Drug Facts	
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	
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	

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



16 fl. oz./473mL

BIOFREEZE[®]

PAIN RELIEVING Spray

WITH SOOTHING MENTHOL

Cryotherapy - The Cold Method[®]



©2010 Performance Health, LLC, Akron, OH 44310
Product No. - BUSASN16-001 • NDC 59316-104-30 • REV 4

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

59316-104-25 Package Label

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



APPLY FROM ANY ANGLE

EVEN SPRAYS UPSIDE DOWN

NO NSAIDs, IBUPROFEN, ASPIRIN OR SALICYLATE



12149 REV 1 • NDC 59316-104-25

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1245 Home Avenue
Akron, OH 44310
www.biofreeze.com

DOT 2P M5665



Drug Facts

Active Ingredients Menthol USP 10%	Purpose 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	
Contents Under Pressure. Do Not Puncture Or Incinerate. Do Not Store At Temperature Above 120° F	
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	
Inactive Ingredients: Arnica Montana Flower Extract, Calendula Officinalis Flower Extract, Chamomile Recutita (Matricaria) Flower Extract, Dimethyl Sulfone (MSM), Echinacea Angustifolia Extract, Alodiol Denal, Yax Paraguensis Leaf Extract, Isopropyl Myristate, Juniperus Communis Fruit Extract, Water, Camellia Sinesis Leaf Extract	
Questions or Comments? 1-800-246-3733	
No Animal Testing	Manufactured in the U.S.A.

for arthritis, back pain, sore muscles and joints

BIOFREEZE®
COLD THERAPY PAIN RELIEF



4 fl oz / 118 mL

SOOTHING MENTHOL • VANISHING SCENT • PARABEN-FREE

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 (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	100 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
ARNICA MONTANA (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 not final	part348	11/01/2010	

Labeler - Performance Health LLC (794324061)

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		557434805	manufacture(59316-104)

Establishment

Name	Address	ID/FEI	Business Operations
Cosmetic Essence, LLC.		825646862	manufacture(59316-104)