

BIOFREEZE - menthol spray
Performance Health, Inc.

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

Drug Facts

Active Ingredients

Menthol USP 10%

Purpose

Cooling Pain Reliever

Temporary relief from minor aches and pains of sore muscles and joints associated with arthritis, backache, strains and 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 degree Fahrenheit

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 the 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 Oifionalis Flower Extract, Chamomile

Recutita Flower Extract, Dimethyl Sulfone (MSM), Echinacea Angustifolia Extract, Alcohol Derivat., Mex Paraguariensis Leaf Extract, Isopropyl Myristate, Junipenus Communis Fruis Extract, Water, Cameilia Sinensis 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 (R)

COLD THERAPY PAIN RELIEF

SOOTHING MENTHOL

VANISHING SCENT

PARABEN-FREE

4 fl oz / 118 mL

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

APPLY FROM ANY ANGLE

EVEN SPRAYS UPSIDE DOWN

NO NSAID's, IBUPROFEN, ASPIRIN OR SALICYLATE

(C) 2012 Performance Health, LLC

1245 Home Avenue

Akron, OH 44310

www.biofreeze.com

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12140 REV 1 • NDC 59316-104-25

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Stop Use And Ask A Doctor If: Condition worsens, or if symptoms persist for more than 7 days, or clear up and recur.	
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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 (DMSO), Echinacea Angustifolia Extract, Alcohol Denat., Her Paraguensis Leaf Extract, Isopropyl Myristate, Juniperus Communis Fruit Extract, Water, Camellia Sinensis Leaf Extract	
Questions or Comments? 1-800-246-3733	
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BIOFREEZE®

COLD THERAPY PAIN RELIEF

SOOTHING MENTHOL • VANISHING SCENT • PARABEN-FREE

4 fl oz / 118 mL

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 FLOWER (UNII: OZ0E5Y15PZ)	

CALENDULA OFFICINALIS FLOWER (UNII: P0M7O4Y7YD)	
DIMETHYL SULFONE (UNII: 9H4PO4Z4FT)	
ECHINACEA ANGUSTIFOLIA (UNII: VB06AV5US8)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
JUNIPER BERRY (UNII: O84B5194RL)	
WATER (UNII: 059QF0KO0R)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59316-104-25	118 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	01/15/2013	12/31/2018

Labeler - Performance Health, Inc. (794324061)

Revised: 6/2015

Performance Health, Inc.