

BIOFREEZE- menthol gel
Performance Health, 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 Gel

Drug Facts

Active Ingredients

Menthol 4%

Purpose

Cooling Pain Relief

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
- Store in a cool dry place

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

Inactive Ingredients

Aloe Barbadosensis Leaf Extract, Arctium Lappa Root (Burdock) Extract, Arnica Montana Flower Extract, Blue 1, Boswellia Carterii Resin Extract, Calendula Officinalis Extract, Camellia Sinensis Leaf Extract, Camphor, Carbomer, Glycerin, Ilex Paraguariensis Leaf Extract, Isopropyl Alcohol, Isopropyl Myristate, Melissa Officinalis (Lemon Balm) Leaf Extract, Silica, Tocopheryl Acetate, Triethanolamine, Water, Yellow 5

Questions or Comments

1-800-246-3733

Package Labeling:

COLD THERAPY PAIN RELIEF FOR SORE MUSCLES, BACKACHES, SORE JOINTS AND ARTHRITIS
LONG-LASTING • VANISHING SCENT • PARABEN-FREE

*Trusted by pharmacists, physical therapists, chiropractors, massage therapists and podiatrists

Does not contain NSAIDs, Ibuprofen, Aspirin, or Salicylate
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Performance Health, LLC,
1245 Home Avenue,
Akron, OH 44310
www.biofreeze.com
14731
Manufactured in the USA
No Animal Testing

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For best results, use Biofreeze® in combination with care from a health professional. Find one in your area at Biofreeze.com.

Drug Facts		Drug Facts (continued)
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Menthol 4%.....	Cooling Pain Relief	
Uses		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
Temporary relief from minor aches and pains of sore muscles & joints associated with: • arthritis • backache • strains • sprains		
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For external use only. Flammable: Keep away from excessive heat or open flame		
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NDC 59316-102-80

BIOFREEZE
menthol gel

Product Information

BIOFREEZE

menthol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:59316-102	
Route of Administration	TOPICAL			
Active Ingredient/Active Moiety				
Ingredient Name		Basis of Strength	Strength	
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)		MENTHOL	40 mg in 1 mL	
Inactive Ingredients				
Ingredient Name			Strength	
ALOE VERA LEAF (UNII: ZY81Z83H0X)				
ARCTIUM LAPPA ROOT (UNII: 597E9B3Z3)				
ARNICA MONTANA FLOWER (UNII: OZ0E5Y15PZ)				
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)				
CALENDULA OFFICINALIS FLOWER (UNII: P0M7O4Y7YD)				
GREEN TEA LEAF (UNII: W2ZU1RY8B0)				
CARBOXYPOLYMETHYLENE (UNII: 0A5MM307FC)				
GLYCERIN (UNII: PDC6A3C0OX)				
ILEX PARAGUARIENSIS LEAF (UNII: 1Q953B4O4F)				
ISOPROPYL ALCOHOL (UNII: ND2M416302)				
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)				
MELISSA OFFICINALIS LEAF (UNII: 50D2ZE9219)				
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)				
TROLAMINE (UNII: 9O3K93S3TK)				
WATER (UNII: 059QF0K00R)				
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59316-102-80	44 mL in 1 TUBE; Type 0: Not a Combination Product	11/02/2018	
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part348	11/02/2018		

Labeler - Performance Health, LLC (794324061)

Revised: 11/2018

Performance Health, LLC