

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 irritated 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 Barbadensis 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:



BIOFREEZE

COOL THE PAIN

GEL

FAST ACTING MENTHOL PAIN RELIEF

3 FL. OZ. / 89 mL

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
13442 REV5
Manufactured in the USA
No Animal Testing

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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

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Questions or Comments
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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.

NDC 59316-102-12

LOT



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)	
FRANKINCENSE (UNII: R9XLF1R1WM)	
CALENDULA OFFICINALIS FLOWER (UNII: P0M7O4Y7YD)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
CARBOXYPOLYMETHYLENE (UNII: 0A5MM307FC)	
GLYCERIN (UNII: PDC6A3C0OX)	
ILEX PARAGUARIENSIS LEAF (UNII: 1Q953B404F)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
MELISSA OFFICINALIS LEAF (UNII: 50D2ZE9219)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
TROLAMINE (UNII: 9O3K93S3TK)	
WATER (UNII: 059QF0KO0R)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59316-102-12	89 mL in 1 BOTTLE; Type 0: Not a Combination Product	09/19/2016	
2	NDC:59316-102-16	89 mL in 1 BOTTLE, WITH APPLICATOR; Type 0: Not a Combination Product	09/19/2016	
3	NDC:59316-102-28	237 mL in 1 BOTTLE; Type 0: Not a Combination Product	09/19/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	09/19/2016	

Labeler - Performance Health LLC (794324061)