

**BIOFREEZE PROFESSIONAL COLORLESS- menthol, unspecified form gel  
NuCare Pharmaceuticals, 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.*

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**Biofreeze Professional Colorless Gel**

***Drug Facts***

***Active Ingredients:***

Menthol USP 5%

**Purpose**

Cooling Pain Relief

**Uses:**

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

**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 liniment; 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 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 four 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, Boswellia Carterii Resin Extract, Calendula Officinalis Extract, Camellia Sinensis Leaf Extract, Carbomer, Glycerin, Ilex Paraguariensis Leaf Extract, Isopropyl Alcohol, Isopropyl Myristate, Melissa Officinalis (Lemon Balm) Leaf Extract, Silica, Tocopheryl Acetate, Triethanolamine, Water.

**Questions or Comments:**

1-800-246-3733

**Package Labeling:**

**BIOFREEZE PROFESSIONAL COLORLESS**

menthol, unspecified form gel

**Product Information**

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68071-1780(NDC:59316-116)
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety				
Ingredient Name			Basis of Strength	Strength
<b>MENTHOL, UNSPECIFIED FORM</b> (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)			MENTHOL, UNSPECIFIED FORM	50 mg in 1 mL
Inactive Ingredients				
Ingredient Name				Strength
<b>ALOE VERA LEAF</b> (UNII: ZY81Z83H0X)				
<b>ARCTIUM LAPPA ROOT</b> (UNII: 597E9BI3Z3)				
<b>ARNICA MONTANA FLOWER</b> (UNII: OZ0E5Y15PZ)				
<b>FRANKINCENSE</b> (UNII: R9XLF1R1WM)				
<b>CALENDULA OFFICINALIS FLOWER</b> (UNII: P0M7O4Y7YD)				
<b>GREEN TEA LEAF</b> (UNII: W2ZU1RY8B0)				
<b>CARBOXYPOLYMETHYLENE</b> (UNII: 0A5MM307FC)				
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)				
<b>ILEX PARAGUARIENSIS LEAF</b> (UNII: 1Q953B4O4F)				
<b>ISOPROPYL ALCOHOL</b> (UNII: ND2M416302)				
<b>ISOPROPYL MYRISTATE</b> (UNII: 0RE8K4LNJS)				
<b>MELISSA OFFICINALIS LEAF</b> (UNII: 50D2ZE9219)				
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)				
<b>.ALPHA.-TOCOPHEROL ACETATE</b> (UNII: 9E8X80D2L0)				
<b>TROLAMINE</b> (UNII: 9O3K93S3TK)				
<b>WATER</b> (UNII: 059QF0KO0R)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68071-1780-4	120 mL in 1 TUBE; Type 0: Not a Combination Product	08/03/2017	
Marketing Information				
Marketing Category	Application Number or Monograph Citation		Marketing Start Date	Marketing End Date
OTC monograph not final	part348		06/03/2016	

**Labeler** - NuCare Pharmaceuticals,Inc. (010632300)

## Establishment

Name	Address	ID/FEI	Business Operations
NuCare Pharmaceuticals,Inc.		010632300	relabel(68071-1780)