BIOFREEZE PROFESSIONAL COLORLESS ROLL-ON- menthol, unspecified form 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 Professional Colorless Roll-On

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 arthiritis, 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

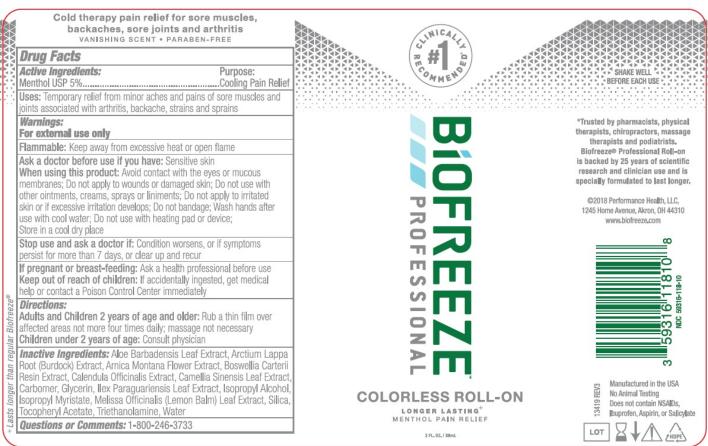
Inactive Ingredients:

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: 59316-118-10



BIOFREEZE PROFESSIONAL COLORLESS ROLL-ON

menthol, unspecified form gel

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:59316-118
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
MENTHOL, UNSPECIFIED FORM (UNII: L7T10 EIP3A) (MENTHOL - UNII:L7T10 EIP3A)	MENTHOL, UNSPECIFIED FORM	50 mg in 1 mL

Inactive Ingredients	
Ingredient Name	Strength
ALOE VERA LEAF (UNII: ZY8 1Z8 3H0 X)	
ARCTIUM LAPPA ROOT (UNII: 597E9BI3Z3)	
ARNICA MONTANA FLOWER (UNII: OZ0E5Y15PZ)	
FRANKINCENSE (UNII: R9 XLF1R1WM)	
CALENDULA OFFICINALIS FLOWER (UNII: P0M7O4Y7YD)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
CARBO XYPO LYMETHYLENE (UNII: 0 A5MM307FC)	
GLYCERIN (UNII: PDC6A3C0OX)	
ILEX PARAGUARIENSIS LEAF (UNII: 1Q953B4O4F)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
ISOPROPYL MYRISTATE (UNII: 0 RE8 K4LNJS)	
MELISSA OFFICINALIS LEAF (UNII: 50 D2ZE9 219)	
SILICON DIO XIDE (UNII: ETJ7Z6XBU4)	
.ALPHATO COPHERO L ACETATE (UNII: 9E8X80D2L0)	
TROLAMINE (UNII: 9O3K93S3TK)	
WATER (UNII: 059QF0KO0R)	

F	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59316-118-10	89 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/03/2016	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	06/03/2016	

Labeler - Performance Health, LLC (794324061)

Revised: 11/2019 Performance Health, LLC