BIOFREEZE PROFESSIONAL COLORLESS- menthol, unspecified form gel
RB Health (US) 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 Gel

Drug Facts

Active Ingredients:

Menthol USP 5%

Purpose

Pain Relieving Gel

Uses:

Temporarily relieves from minor aches and pains of muscles and joints associated with:
• simple backache • arthritis • strains • bruises • sprains

Warnings:

For external use only

Flammable: Keep away from excessive heat or open flame

When using this product:

• Use only as directed • Avoid contact with the eyes or on mucous membranes • Do not apply to wounds or damaged skin • Do not apply to irritated skin or if excessive irritation develops • Do not bandage tightly or use with
heating pad or device

Stop use and ask a doctor If:

You experience pain, swelling or blistering of the skin; condition worsens, or if symptoms persist for more than 7 days, or clear up and occur again within a few days; arthritic pain persists for more than 10 days, or redness is present, or in conditions affecting children under 12 years of age

If pregnant or breast-feeding:

Ask a health professional before use

Keep out of reach of children:

If swallowed, get medical help or contact a Poison Control Center right away.

Directions:

• Adults and Children 2 years of age and older: Rub a thin film over affected areas not more than 3 to 4 times daily;
•Children under 2 years of age: Consult a physician
• wash hands after use with cool water

Other information:

store at 20-25° C (68-77°F) - store in a cool dry place away from direct sunlight

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

PRINCIPAL DISPLAY PANEL - 946 mL Bottle Label

CLINICALLY
RECOMMENDED*

BiOFREEZE®
PROFESSIONAL

NDC 59316-116-40

COLORLESS GEL

MENTHOL-PAIN
RELIEVING GEL

32 FL OZ (1 QT) 946 mL

BIOFREEZE PROFESSIONAL COLORLESS

menthol, unspecified form gel

Product Information

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

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A) (MENTHOL, UNSPECIFIED FORM - UNII:L7T10EIP3A)	MENTHOL, UNSPECIFIED FORM	50 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
ARCTIUM LAPPA ROOT (UNII: 597E9BI3Z3)	
ARNICA MONTANA FLOWER (UNII: OZ0E5Y15PZ)	
FRANKINCENSE (UNII: R9XLF1R1WM)	
CALENDULA OFFICINALIS FLOWER (UNII: P0M7O4Y7YD)	

GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (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)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
TROLAMINE (UNII: 9O3K93S3TK)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59316-116-11	3 mL in 1 PACKET; Type 0: Not a Combination Product	06/03/2016	12/31/2020
2	NDC:59316-116-20	118 mL in 1 TUBE; Type 0: Not a Combination Product	06/03/2016	
3	NDC:59316-116-40	946 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 - RB Health (US) LLC (081049410)

Revised: 1/2022 RB Health (US) LLC