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



COLORLESS GEL MENTHOL-PAIN RELIEVING GEL

32 FL 0Z (1 QT) 946 mL

NDC 59316-116-40

MUSCLES, AND JOINTS, SIMPLE BACKACHES. ARTHRITIS, STRAINS, BRUISES AND SPRAINS.



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Drug Facts

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Other Information
store at 20-25°C (88-77°F) store in a cool dry place away from direct sunlight

Inactive Ingredients
Also Barbadensis Listi Etruck, Archum Lappa Root (Burdod) Extract, Armica Montana.
Rower Extract, Bowellia Carleri Reani Extract, Calendula Officinalia Extract, Camellia
Shessis Leaf Extract, Cantomer, Blycarin, User Paraguariensis Leaf Extract, Isopropyl
Aschola, Isopropyl Myristala, Meliesa Officinalia (Lemon Balm) Leaf Extract, Silica,
Tocophenyl Acelsia, Trieshausclamie, Walter

#2022 PB Heelth "Based on a survey of Clinidure: chiropradors, podistriata, massage Dist. by: RB Health (LB) theraptets, physical theraptets, retail phurmacista, and athletic traine prepayeny, NJ 07064-0224 [PSOS Clinician Survey).

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)

50 mg MENTHOL, UNSPECIFIED FORM 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)	
.ALPHATOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
TROLAMINE (UNII: 903K93S3TK)	
WATER (UNII: 059QF0KO0R)	

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

Labeler - RB Health (US) LLC (081049410)

Revised: 1/2022 RB Health (US) LLC